September 1996
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# RESPIRATORY CARE

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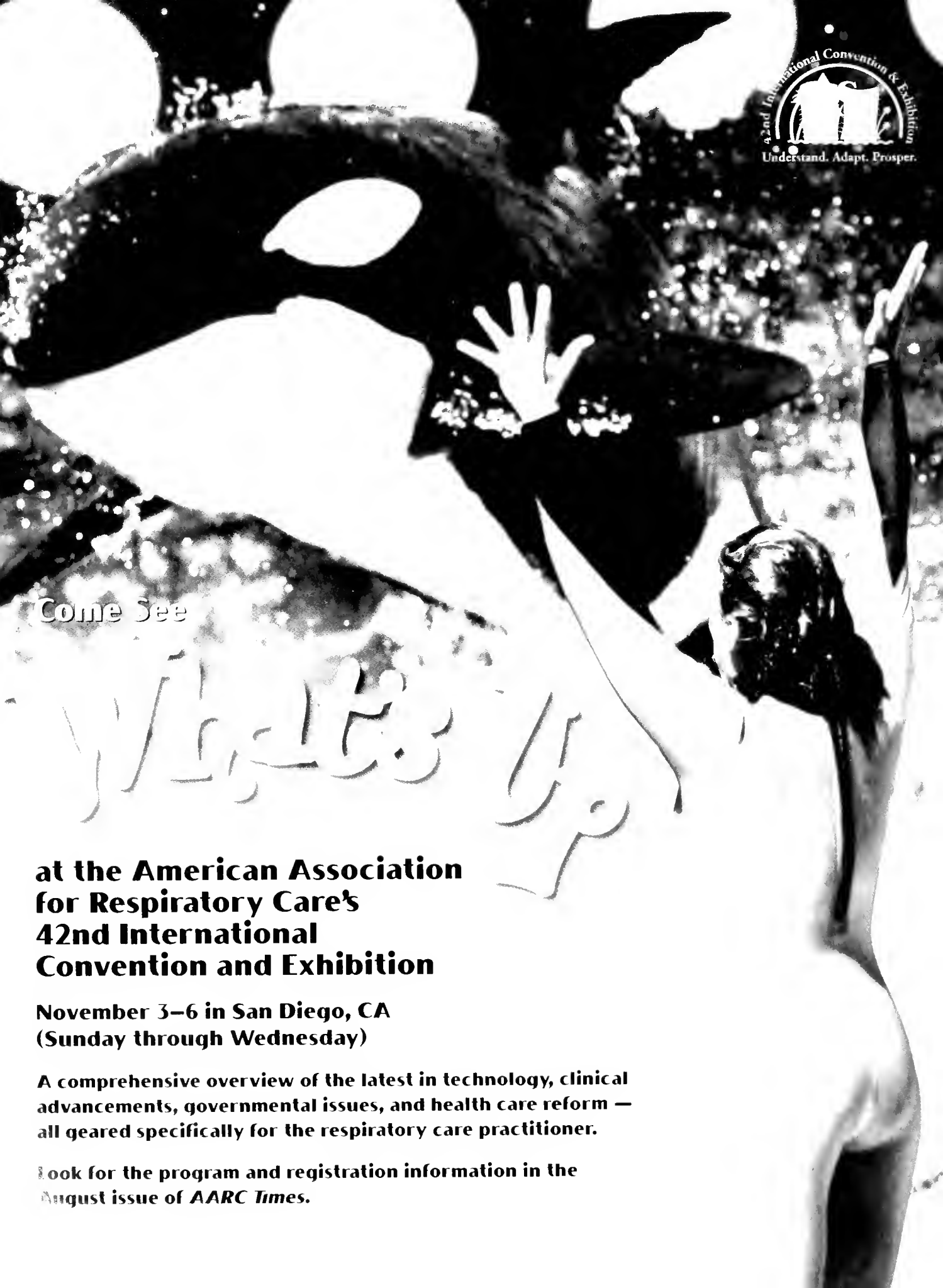


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836 Retrospectroscope Redux: Speculation on Speculation
*by Julius H Comroe Jr (Reprinted, with permission, from Am Rev Respir Dis 1977;115:343-349.)*

## CORRECTION

828 Corrected Equation Sequence
*Equations 14-18, in Appendix 1 of Granger WM, A SCoP computer model of steady-state gas exchange: evaluating the oxygen-tension-based indices of venous admixture. Respir Care 1996;41(7):586-594.*

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**Editorials, Commentaries, and Reviews To Note**

**Asthma: The Important Questions, Part 3** (Supplemental Issue)—Am J Respir Crit Care Med 1996;153(6, Part 2):S1-S32.

**The Genetics of Asthma** (State of the Art)—A Sandford, T Weir, P Paré. Am J Respir Crit Care Med 1996; 153(6):1749-1765.

**Issues in the Use of Inhaled Glucocorticoids** (Pulmonary Perspective)—AK Kamada, SJ Szefler, RJ Martin, HA Boushey, VM Chinchilli, JM Drazen, JE Fish, E Israel, SC Lazarus, RF Lemanske, and the Asthma Clinical Research Network. Am J Respir Crit Care Med 1996;153(6):1739-1748.

**Dyspnea Ratings for Prescribing Exercise Intensity in Patients with COPD**—MB Horowitz, B Littenberg, DA Mahler. Chest 1996; 109(5):1169-1175.

OBJECTIVE: We tested the hypothesis that patients with COPD can use dyspnea ratings obtained from a prior graded exercise test as a target to reliably produce specific exercise intensities. DESIGN: Four visits over a 7-week period. SETTING: Pulmonary function and cardiorespiratory exercise laboratory at a university hospital. PATIENTS: Fifteen symptomatic patients with stable COPD. Age was 68 ± 7 (mean ± SD) years. $FEV_1$ was 1.12 ± 0.22 L (45 ± 8% predicted). INTERVENTIONS: At each visit, patients estimated the heaviness of weights to evaluate their magnitude estimation of a nonrespiratory task; after pulmonary function testing was completed, patients were tested on the cycle ergometer. At estimation trial 1 (day 0), patients estimated the intensity of dyspnea using the 0 to 10 category-ratio scale during an incremental exercise test. Estimation trial 2 (day 5 to 7) was the same as the previous trial. At production trials 1 (day 10 to 14) and 2 (day 40 to 44), patients were instructed to produce specific intensities of dyspnea (ie, dyspnea targets) at 50% and at anaerobic threshold (AT) or 80% of peak oxygen consumption ($\dot{V}_{O_2}$) as calculated from results at estimation trial 2. MEASUREMENTS & RESULTS: Lung function was stable at all visits. Dyspnea ratings were 1.8 ± 0.9 (range, 1 to 3) at 50% of peak $\dot{V}_{O_2}$ and 5.5 ± 1.5 (range, 4 to 8) at AT/80% of peak $\dot{V}_{O_2}$ (17.0 ± 3.4 mL/kg/min) at estimation trial 2. The individual percent changes in $\dot{V}_{O_2}$ at the lower dyspnea target were 12 ± 19% and 11 ± 19% for production trials 1 and 2, respectively, compared with estimation trial 2. At the higher dyspnea target, the corresponding individual percent changes in $\dot{V}_{O_2}$ were −4 ± 9% and −7 ± 11%, respectively. For all 15 patients, there were borderline statistical differences for the $\dot{V}_{O_2}$ values at the lower ($p = 0.04$ and $p = 0.07$) and at the higher ($p = 0.04$ for each production trial) dyspnea targets for production trials 1 and 2 compared with estimation trial 2. Two patients showed 50% or greater variability in the calculated exponent for magnitude estimation of weights. In a subgroup analysis of the 13 patients with reproducible magnitude estimation of the heaviness of weights, there were no significant differences in $\dot{V}_{O_2}$ for the 2 production trials compared with estimation trial 2 at both exercise intensities. CONCLUSIONS: Dyspnea ratings obtained from an incremental exercise test can be used as a target for patients with COPD to regulate/monitor the intensity of exercise training. The ability of patients with COPD to achieve a desired $\dot{V}_{O_2}$ based on an individual dyspnea target was generally more accurate at the higher exercise level (AT/80% of peak $\dot{V}_{O_2}$) compared with the lower intensity (50% of peak $\dot{V}_{O_2}$). Acceptable accuracy was maintained over a 5-week time period.

**Economic Cost of Home-Based Care for Ventilator-Assisted Individuals: A Preliminary Report**—MA Sevick, MS Kamlet, LA Hoffman, I Rawson. Chest 1996;109(6):1597-1606.

OBJECTIVE: To measure the direct and indirect costs of maintaining a ventilator-assisted individual (VAI) at home. DESIGN: A cross-sectional survey was conducted of primary family caregivers of VAIs residing in 37 states. SETTING: Surveys were delivered to the homes of VAIs. PARTICIPANTS: Two hundred seventy-seven (19.7%) of 1,404 primary family caregivers of patients who were ventilator-dependent and who were living at home. INTERVENTIONS: None. MEASURES: Participants received the modified Katz Index and an investigator-developed Home Ventilator Care Cost and Utilization Survey (HVCCUS). RESULTS: Total cost of care was determined by summing total direct medical and nonmedical costs of home care and lost wages. Using LPN rates for private duty care, the average total cost of care was estimated to be $7,642 per month (median = $5,406). Using RN rates for private duty care, the average total cost of home care was estimated to be $8,596 per month (median = $5,911). Variation with VAI characteristics is discussed. CONCLUSIONS: Home care of VAIs is a labor-intensive and an economically costly undertaking. The development of policies and programs to support home placement requires additional investigation regarding factors affecting the cost-effectiveness of various placement settings, as well as the ability and/or willingness of family members to accept the cost and responsibility of home care.

**A Crossover Study Comparing the Efficacy of Continuous Positive Airway Pressure with Anterior Mandibular Positioning Devices on Patients with Obstructive Sleep Apnea**—GT Clark, I Blumenfeld, N Yoffe, E Peled, P Lavie. Chest 1996;109(6):1477-1483.

OBJECTIVE: This study compared the efficacy of a removable anterior mandibular positioning (AMP) device to continuous positive airway pressure (CPAP) in patients with obstructive sleep apnea (OSA) using a fully balanced crossover design. DESIGN: Twenty-three male subjects with confirmed OSA were recruited from the Technion Sleep Laboratory in Haifa, Israel, from February 18, 1991 to December 17, 1992. Twenty-one of the 23 subjects enrolled completed all aspects of the study. RESULTS: The mean apnea-hypopnea index (AHI) before treatment was 33.86 ± 14.30. The mean AHI decreased with CPAP to 59.50%, but decreased only 38.91% with the AMP device. The lowest mean recorded oxygen saturation level for the 21 subjects was 84.30 before treatment, 91.10 after CPAP treatment, and 90.20 after AMP treatment. Sleep data revealed a sig-

nificant decrease in stage 1 and 2 ($p = 0.0088$) and an increase in rapid eye movement percent ($p = 0.0066$) for both treatments when compared with baseline. Three- to 10-month post-treatment phone interviews showed that 1 subject was not using either device, 1 subject was using CPAP, and 2 subjects were using the AMP device intermittently due to occasional temporomandibular joint pain symptoms. The remaining 17 subjects were all using the AMP device nightly. The symptoms of excessive daytime sleepiness also decreased significantly by both AMP and CPAP. CONCLUSIONS: The AMP device achieved substantial success in most cases, but was less effective than CPAP, especially for the more severe cases. In general, the AMP device was strongly preferred over the CPAP by the subjects of this study.

**Pathologic Changes of the Trachea after Percutaneous Dilatational Trachentomy**—LWE van Heurn, PHMH Theunissen, G Ramsay, PRG Brink. Chest 1996;109(6):1466-1469.

The tracheas of 12 patients who had undergone autopsies after percutaneous dilatational tracheotomy (PDT) were analyzed macroscopically and microscopically. The puncture site of the trachea varied from just below the cricoid cartilage (2 patients) to below the third ring (3 patients). A fracture of one or more tracheal rings was present in 11 patients, of whom 2 had a fractured cricoid. Destruction of one or more tracheal rings was present in all 8 patients cannulated for more than 10 days and was related to duration of cannulation ($p < 0.005$). Protrusion of the anterior wall into the tracheal lumen with tracheal stenosis was seen in 2 patients. Improvements to the PDT technique are discussed to avoid complications.

**Self-Reported Use of CPAP and Benefits of CPAP Therapy: A Patient Survey**—HM Engleman, N Asgari-Jirhandeh, AL McLeod, CF Ramsay, IJ Deary, NJ Douglas. Chest 1996;109(6):1470-1476.

The benefits of continuous positive airway pressure (CPAP) therapy in patients with the sleep apnea/hypopnea syndrome (SAHS) are poorly documented and patients use CPAP less than physicians recommend. To establish patients' perceptions of benefit from CPAP and to identify determinants of CPAP use, 204 CPAP users completed a questionnaire relating to use of CPAP therapy, sleepiness, and road traffic incident rate before and after CPAP, perceived change in daytime function and nocturnal symptoms with treatment, and problems with CPAP. Variables from these domains of interest were examined, reduced through principal components analysis and correlated to assess associations between these and polysomnographic measures of illness severity. Self-reported CPAP use averaged 5.8 ± SD 2 hours a night. Subjective sleepiness rated by the Epworth sleepiness scale and road traffic incident rate were significantly reduced by CPAP ($p < 0.0001$). A broad range of function and symptom items were highly significantly improved with CPAP ($p < 0.0001$), corroborating the cost to community and industry from SAHS and the preventive value of CPAP. Road traffic incident rate before treatment was correlated with pre-CPAP sleepiness and SAHS severity. Subjective CPAP use correlated with sleepiness before treatment but not with SAHS severity. CPAP mask problems and side effects were not associated with reduced CPAP use, but "nuisance" complaints of awakenings, noise, and sore eyes from CPAP correlated negatively with reported use. Greater reported CPAP use was associated with better resolution of sleepiness and greater improvement in daytime function and nocturnal symptoms. *See the related editorial: **OSA and Cardiovascular Morbidity: Will CPAP Prove To Be Effective?**—CW Zwillich. Chest 1996;109(6)1416-1417.*

**A Randomized Crossover Study of an Oral Appliance versus Nasal-Continuous Positive Airway Pressure in the Treatment of Mild-Moderate Obstructive Sleep Apnea**—KA Ferguson, T Ono, AA Lowe, SP Keenan, JA Fleetham. Chest 1996;109(5):1269-1275.

OBJECTIVE: To compare efficacy, side effects, patient compliance, and preference between oral appliance (OA) therapy and nasal-continuous positive airway pressure (N-CPAP) therapy. DESIGN: Randomized, prospective, crossover study. SETTING: University hospital and tertiary sleep referral center. PATIENTS: Twenty-seven unselected patients with mild-moderate obstructive sleep apnea (OSA). INTERVENTIONS: There was a 2-week wash-in and a 2-week wash-out period, and 2 × 4-month treatment periods (OA and N-CPAP). Efficacy, side effects, compliance, and preference were evaluated by a questionnaire and home sleep monitoring. MEASUREMENTS & RESULTS: Two patients dropped out early in the study and treatment results are presented on the remaining 25 patients. The apnea/hypopnea index was lower with N-CPAP (3.5 ± 1.6) (mean ± SD) than with the OA (9.7 ± 7.3) ($p < 0.05$). Twelve of the 25 patients who used the OA (48%) were treatment successes (reduction of apnea/hypopnea to < 10/hour and relief of symptoms), 6 (24%) were compliance failures (unable or unwilling to use the treatment), and 7 (28%) were treatment failures (failure to reduce apnea/hypopnea index to <10/hour and/or failure to relieve symptoms). Four people refused to use N-CPAP after using the OA. Thirteen of the 21 patients who used N-CPAP were overall treatment successes (62%), 8 were compliance failures (38%), and there were no treatment failures. Side effects were more common and the patients were less satisfied with N-CPAP ($p < 0.005$). Seven patients were treatment successes with both treatments, 6 of these patients preferred OA, and one preferred N-CPAP as a long-term treatment. CONCLUSIONS: We conclude that OA is an effective treatment in some patients with mild-moderate OSA and is associated with fewer side effects and greater patient satisfaction than N-CPAP.

**Evaluation of Heliox in Children Hospitalized with Acute Severe Asthma: A Randomized Crossover Trial**—ER Carter, CR Webb, DR Moffitt. Chest 1996;109(5):1256-1261.

OBJECTIVE: To determine whether breathing a blend of 70% helium:30% oxygen (heliox) would improve pulmonary function, decrease clinical score, and improve the sensation of dyspnea in children hospitalized with acute severe asthma. DESIGN: Prospective, randomized, double-blind, crossover study. SETTING: The inpatient pediatric service of a military, tertiary care, teaching hospital. PATIENTS: Children 5 to 18 years who required hospital admission for treatment of acute asthma. INTERVENTIONS: All patients received 5 mg of nebulized albuterol every 1 to 4 hours, with a dose given within 30 minutes of the start of the study, and I.V. administered methylprednisolone. Patients breathed heliox and a 30% oxygen-enriched air mixture for 15 minutes each in

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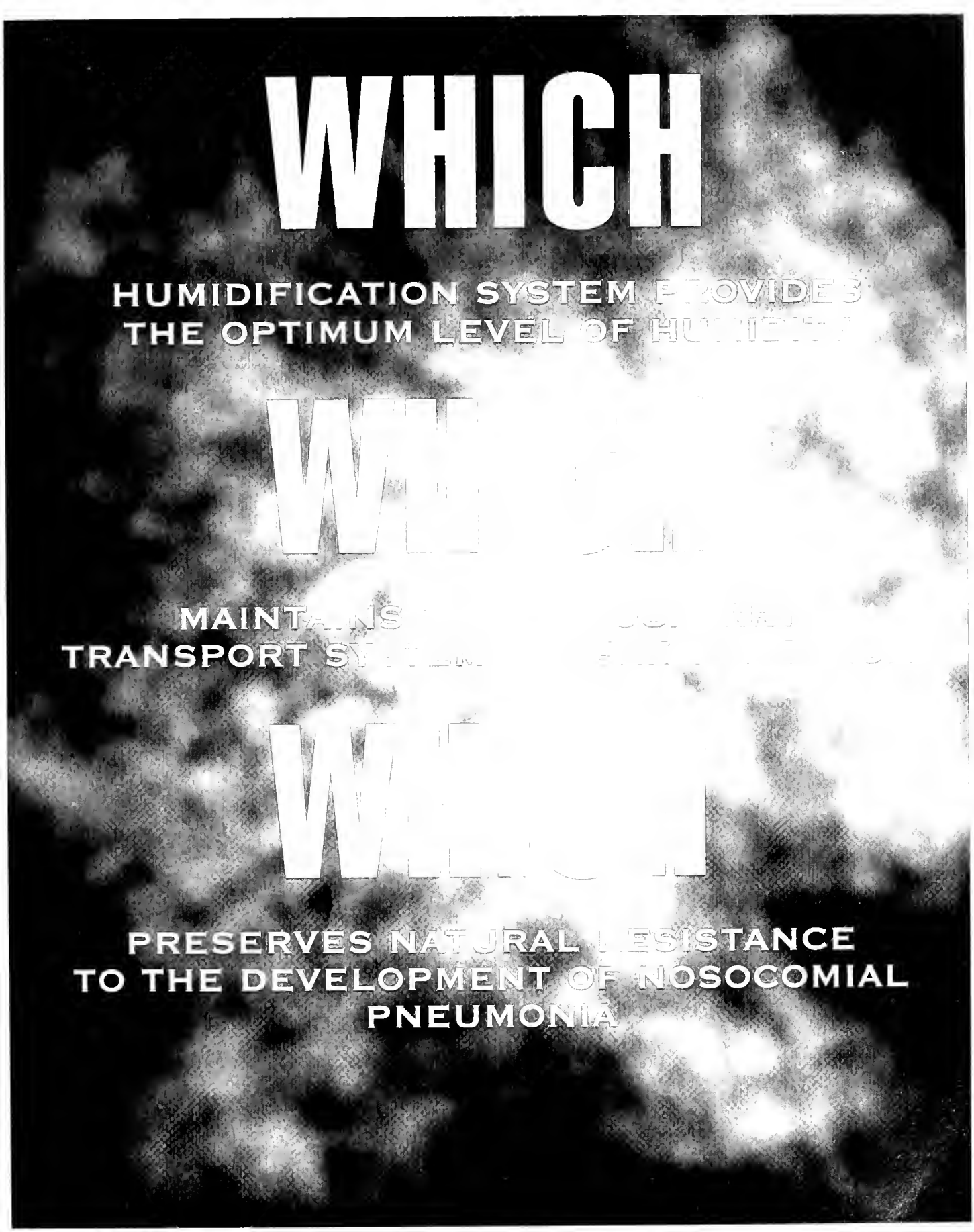


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random order. MEASUREMENTS & RESULTS: Clinical score, dyspnea score, oxygen saturation, heart rate, and respiratory rate, followed by FVC, $FEV_1$, peak expiratory flow rate (PEFR), and, mean midexpiratory flow rate ($FEF_{25-75}$) were obtained at study entry, 15 minutes after breathing the first gas mixture (heliox or air per randomization), 15 minutes after breathing the second mixture, and again 15 minutes after stopping the second gas mixture (study end values). Eleven children were enrolled, and all completed the study. There were no significant differences between study entry and study end spirometric values. Using the paired *t* test, we found no significant differences between mean values (SD) of $FEV_1$ and FVC obtained while breathing heliox versus air; $FEV_1$-heliox, 53% (18%) of the predicted value; $FEV_1$-air, 52% (16%) of the predicted value ($p = 0.36$); FVC-heliox, 69% (22%) of the predicted value; and FVC-air, 70% (21%) of the predicted value ($p = 0.50$). The differences in values for PEFR and $FEF_{25-75}$ while breathing heliox versus air were small but did reach statistical significance in favor of heliox: PEFR-heliox, 56% (20%) of the predicted value; PEFR-air, 50% (16%) of the predicted value ($p = 0.04$); $FEF_{25-75}$-heliox, 32% (13%) of the predicted value; and $FEF_{25-75}$-heliox, 29% (11%) of the predicted value ($p = 0.006$). Heliox had no effect on either clinical or dyspnea scores. CONCLUSION: The short-term inhalation of heliox did not benefit this group of children hospitalized with acute, severe asthma.

**Spirometry and Dyspnea in Patients with COPD: When Small Differences Mean Little**—DA Redelmeier, RS Goldstein, ST Min, RH Hyland. Chest 1996;109(5):1163-1168.

OBJECTIVE: To determine when a difference in $FEV_1$ is sufficiently large to be associated with a noticeable difference in dyspnea symptoms for patients with chronic lung disease. DESIGN: Cross-sectional analysis of 15 groups (n = 112 patients, 832 contrasts). SETTING: Respiratory rehabilitation program. PATIENTS: Patients with COPD (mean $FEV_1$ = 35% predicted). MEASURES: Patients' perspectives assessed through subjective comparison ratings of dyspnea and of overall health. Relation between the $FEV_1$ and patients' perspectives determined the smallest difference in spirometry that was associated with a noticeable difference in patients' symptoms. RESULTS: The $FEV_1$ was moderately correlated with patients' ratings of dyspnea ($r = 0.29$; 95% confidence interval (CI), 0.22 to 0.35). In contrast, the $FEV_1$ was minimally correlated with patients' ratings of overall health ($r = 0.10$; 95% CI, 0.03 to 0.17). The $FEV_1$ needed to differ by 4% predicted for the average patient to stop rating his or her dyspnea as "about the same" and start rating his or her dyspnea as either "a little bit better" or "a little bit worse" relative to other patients (95% CI, 1.5 to 6.5). This was equivalent to the average patient's $FEV_1$ increasing by 112 mL (starting from 975 mL and ending at 1,087 mL). CONCLUSIONS: Some statistically significant differences in the $FEV_1$ are so small that they may not represent important differences in symptoms for the average patient with severe COPD; an awareness of the smallest difference in $FEV_1$ that is noticeable to patients can help clinicians interpret the effectiveness of symptomatic treatments.

**Critical Illness Myopathy and Neuropathy**—N Latronico, F Fenzi, D Recupero, B Guarneri, G Tomelleri, P Tonin, G De Maria, L Antonini, N Rizzuto, A Candiani. Lancet 1996;347(9015):1579-1582.

BACKGROUND: Critically ill patients may develop muscle weakness or paralysis during the


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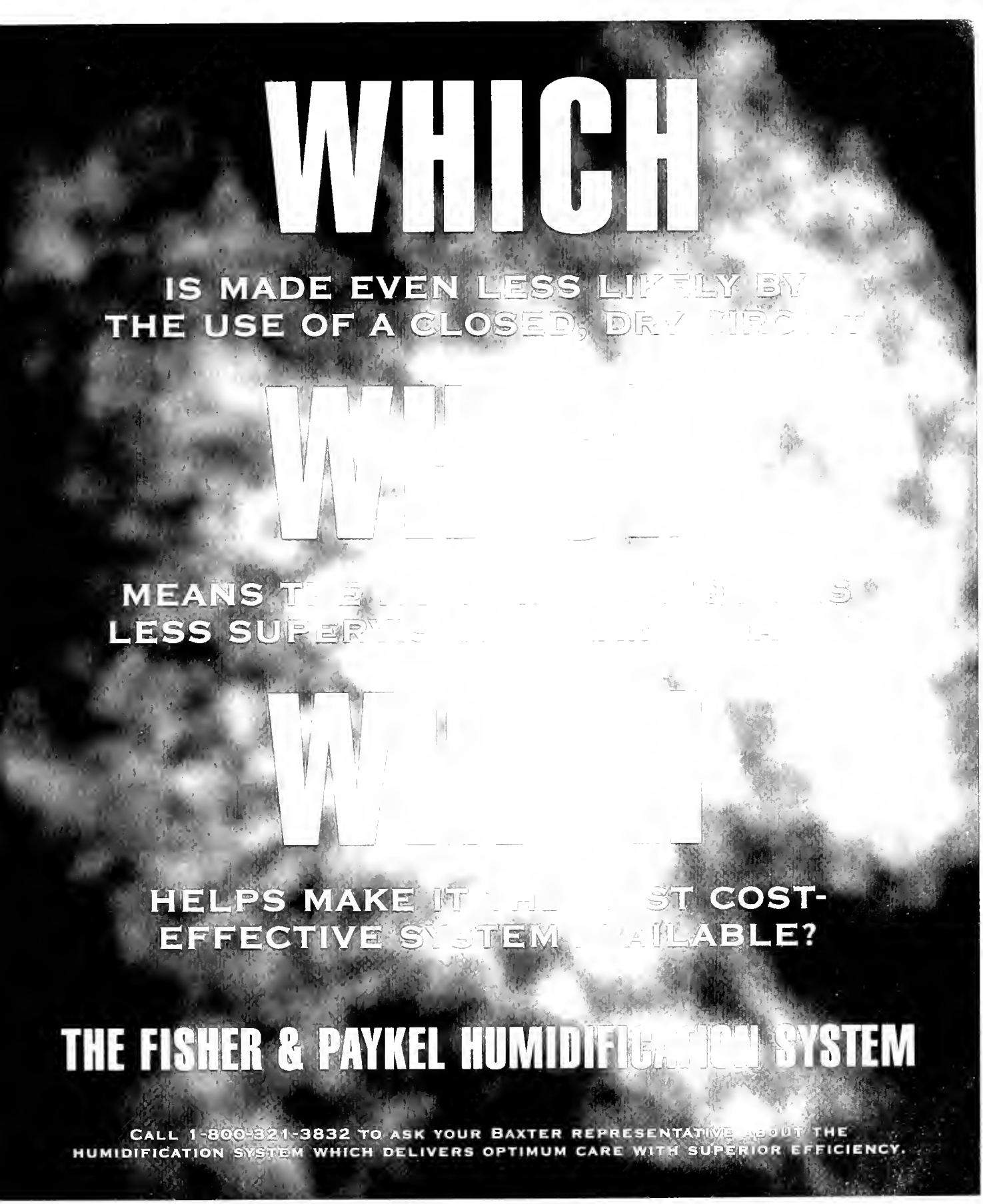


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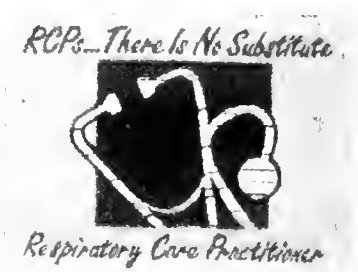


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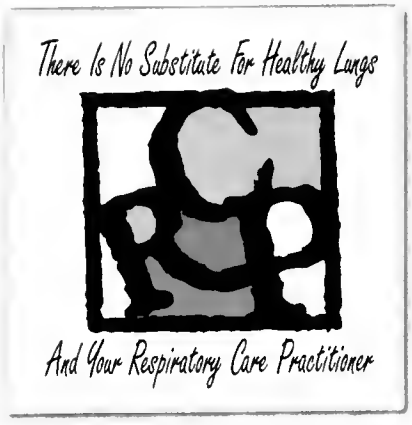


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course of sepsis and multiple-organ failure. We studied peripheral nerve and muscle disorders (NMD) in comatose patients. METHODS: Comatose patients who developed paralysis associated with absent deep-tendon reflexes had electroneuromyography (ENMG) and muscle-nerve biopsy specimens taken. Onset and duration of sepsis, multiple-organ dysfunction and failure, biochemical alterations, and drugs potentially interfering with nerve-muscle function were recorded. FINDINGS: 24 patients became quadriparetic or quadriplegic; muscle changes were found in 23. Axonal neuropathy was found in 8 of 22 patients examined. All patients had prolonged sepsis and multiple-organ dysfunction, but only 14 had multiple-organ failure. Drugs such as steroids, neuromuscular-blocking agents, and aminoglycosides were not responsible for paresis, and the part played by hyperglycaemia and hypoalbuminaemia is uncertain. Attending physicians predicted a fatal outcome in all cases, although 6 of 7 survivors fully recovered within 115-210 days from the onset of paralysis. INTERPRETATION: Comatose patients may become completely paralysed because of NMD. The diagnosis is important to avoid unnecessary investigations and unreasonably pessimistic prognosis. ENMG is essential for the diagnosis and for planning further clinical management. Biopsy needs to be done only when it is necessary to properly classify NMD.

**The Cost of Prematurity: A Case-Control Study of Twins versus Singletons**—B Luke, HR Bigger, S Leurgans, D Sietsema. Am J Public Health 1996;86(6):809-814.

OBJECTIVES: This study evaluated the extent to which morbidity and costs at birth were associated with plurality, gestational age, and birthweight with a sample of twins from a large urban hospital. METHODS: Each twin infant was matched to 2 singleton infants (control [ctrl]-singletons) for payor status and race, and to one singleton infant (gestation [ga]-singleton) for payor status, race, and gestational age; after exclusion of infants who were transferred, the study population included 111 twins, 242 ctrl-singletons, and 106 ga-singletons. Data were stratified by 5 gestational categories and compared across study groups. Outcomes included birthweight, neonatal diagnoses, infant length of stay, infant costs per day, and total infant and total birth costs. RESULTS: Total birth costs ranged from $280,146 at 25 to 27 weeks to $9,803 at 39 to 42 weeks, decreasing with advancing gestation to means of $88,891 (twins), $43,041 (ga-singletons), and $9,326 (ctrl-singletons). Twins did not differ from either group of singletons in prematurity-related diagnoses, length of stay, or costs until after 34 weeks' gestation. CONCLUSIONS: In this sample, prematurity, not plurality, was the predominant cost factor at birth. Compared with singletons, twins experienced increased morbidity and associated costs after 38 weeks' gestation.

**Differences in the Misreporting of Chronic Conditions, by Level of Education: The Effect on Inequalities in Prevalence Rates**—JP Mackenbach, CWN Looman, JBW van der Meer. Am J Public Health 1996;86(5):706-711.

OBJECTIVES: Many studies of socioeconomic inequalities in the prevalence of chronic conditions rely on self-reports. For chronic nonspecific lung disease, heart disease, and diabetes mellitus, we studied the effects of misreporting on variations in prevalence rates by respondents' level of education. METHODS: In 1991, a health interview survey was conducted in the southeastern Netherlands with 2,867 respondents. Respondents' answers were compared with validated diagnostic


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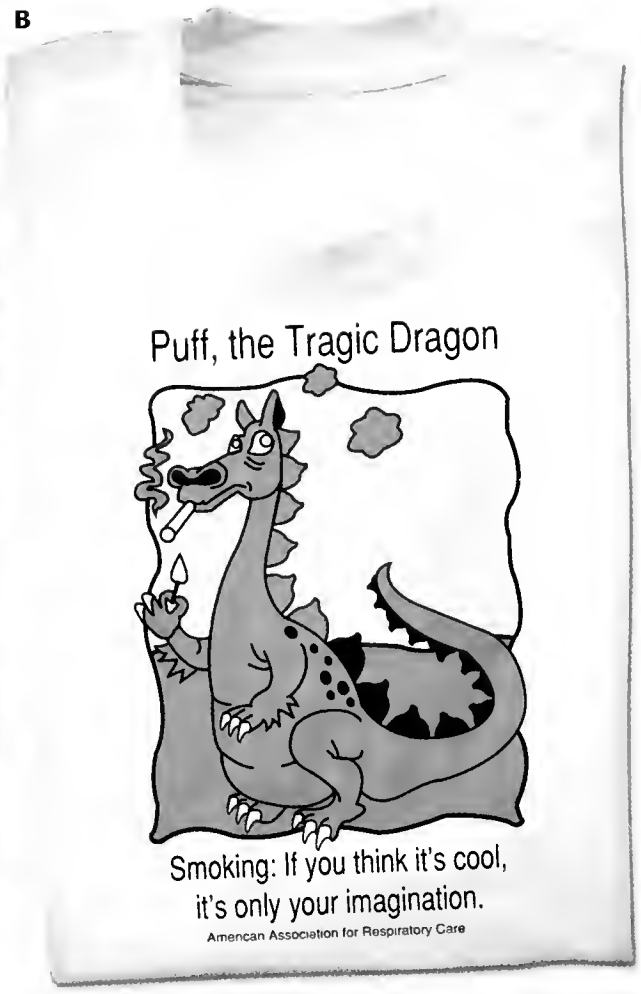


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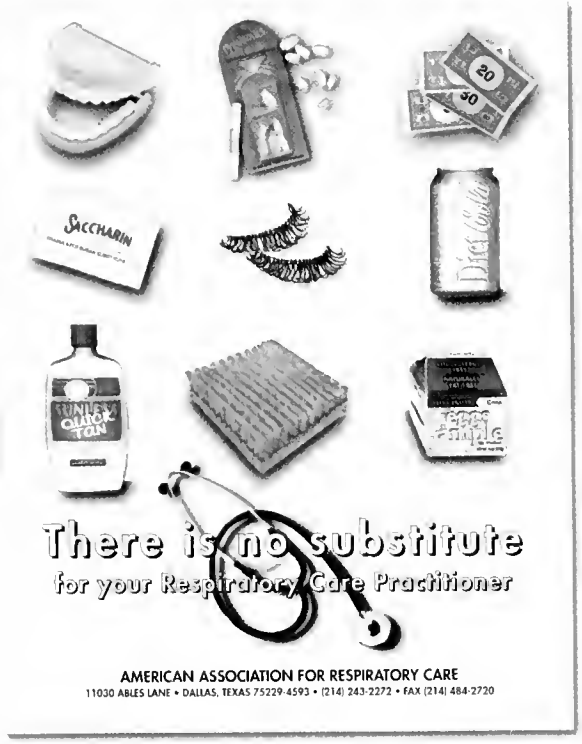


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questionnaires in the same survey and the diagnoses given by the respondents' general practitioners. RESULTS: Misreporting of chronic lung disease, heart disease, and diabetes may be extensive. Depending on the condition and the reference data used, the confirmation fractions ranged between 0.61 and 0.96 and the detection fractions between 0.13 and 0.93. Misreporting varied by level of education, and although various patterns were observed, the dominant pattern was that of more underreporting among less educated persons. The effects on prevalence rates were to underestimate differences by level of education to a sometimes considerable degree. CONCLUSIONS: Misreporting of chronic conditions differs by respondents' level of education. Health interview survey data underestimate socioeconomic inequalities in the prevalence of chronic conditions.

**Comparison of Oxygen Saturation by Pulse Oximetry and Co-Oximetry during Exercise Testing in Patients with COPD**—JP McGovern, SA Sasse, DW Stansbury, LA Causing, RW Light. Chest 1996;109(5):1151-1155.

INTRODUCTION: Measurement of oxygen saturation by pulse oximetry ($S_{pO_2}$) is frequently performed during exercise testing of patients with COPD to monitor for hypoxemia. The purpose of this study was to assess the accuracy and precision of pulse oximetry during exercise. We hypothesized that the $S_{pO_2}$ would more closely reflect oxygen saturation as measured by co-oximetry ($S_{aO_2}$) when it was corrected for carboxyhemoglobin (COHb). We also hypothesized that $S_{pO_2}$ would more closely reflect $S_{aO_2}$ when the pulse rate by oximeter was equivalent to the heart rate by ECG. Finally, we hypothesized that $S_{pO_2}$ would be a better measure of $S_{aO_2}$ at maximal workloads than at rest or submaximal workloads. METHODS: Eight white men with severe COPD (mean ± SD $FEV_1$, 0.91 ± 0.37) underwent progressive, symptom-limited exercise testing by cycle ergometry. $S_{aO_2}$ was measured from arterial blood at each workload using a co-oximeter. $S_{pO_2}$ and pulse rate were obtained by a pulse oximeter (Ohmeda 3700). Heart rate was continuously monitored by ECG. RESULTS: Reliable oximetric values as determined by a dicrotic notch in each waveform and adequate signal intensity were obtained in all 8 patients. $S_{pO_2}$ was a moderately accurate measure of $S_{aO_2}$ (bias, 1.7%; precision, 2.9). The bias actually increased (4.1%) when $S_{pO_2}$ was corrected for COHb. Accuracy of $S_{pO_2}$ was not improved when pulse rate by oximetry and heart rate by ECG were equivalent, nor was the accuracy improved at maximal workloads relative to submaximal workloads during the exercise test. CONCLUSION: Oxygen saturation as measured by pulse oximetry ($S_{pO_2}$) in patients with COPD undergoing exercise testing is not sufficiently accurate to replace $S_{aO_2}$ as the gold standard for oxygen saturation.

**The Ontario Trial of Active Compression-Decompression Cardiopulmonary Resuscitation for In-Hospital and Prehospital Cardiac Arrest**—IG Stiell, PC Hébert, GA Wells, A Laupacis, K Vandemheen, JF Dreyer, MA Eisenbauer, J Gibson, LAJ Higginson, AS Kirby, JL Mahon, JP Maloney, BN Weitzman. JAMA 1996;275(18): 1417-1423.

OBJECTIVE: To compare the impact of active compression-decompression (ACD) cardiopulmonary resuscitation (CPR) and standard CPR on the outcomes of in-hospital and prehospital victims of cardiac arrest. DESIGN: Randomized controlled trial with blinding of allocation using a sealed container. SETTINGS: (1) Emergency departments, wards, and intensive care units of


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5 university hospitals and (2) all locations outside hospitals in 2 midsized cities. PATIENTS: A total of 1,784 adults who had cardiac arrest. INTERVENTION: Patients received either standard or ACD CPR throughout resuscitation. MAIN OUTCOME MEASURES: Survival for 1 hour and to hospital discharge and the modified Mini-Mental State Examination (MMSE). RESULTS: All characteristics were similar in the standard and ACD CPR groups for the 773 in-hospital patients and the 1,011 prehospital patients. For in-hospital patients, there were no significant differences between the standard (n = 368) and ACD (n = 405) CPR groups in survival for 1 hour (35.1% vs 34.6%; p = 0.89), in survival until hospital discharge (11.4% vs 10.4%; p = 0.64), or in the median MMSE score of survivors (37 in both groups). For patients who collapsed outside the hospital, there were also no significant differences between the standard (n = 510) and ACD (n = 501) CPR groups in survival for 1 hour (16.5% vs 18.2%; p = 0.48), in survival to hospital discharge (3.7% vs 4.6%; p = 0.49), or in the median MMSE score of survivors (35 in both groups). Exploration of clinically important subgroups failed to identify any patients who appeared to benefit from ACD CPR. CONCLUSIONS: ACD CPR did not improve survival or neurologic outcomes in any group of patients with cardiac arrest.

**The Influence of the Wider Use of Surfactant Therapy on Neonatal Mortality among Blacks and Whites**—A Hamvas, PH Wise, RK Yang, NS Wampler, A Noguchi, MM Maurer, CA Walentik, WF Schramm, FS Cole. N Engl J Med 1996;334(25):1635-1640

BACKGROUND: Surfactant therapy reduces morbidity and mortality among premature infants with the respiratory distress syndrome (RDS). Fetal pulmonary surfactant matures more slowly in white than in black fetuses, and therefore RDS is more prevalent among whites than among blacks. We reasoned that the increased use of surfactant after its approval by the Food and Drug Administration (FDA) in 1990 might have reduced neonatal mortality more among whites than among blacks. METHODS: We merged vital-statistics information for all 1,563 infants with very low birthweights (500 to 1,500 g) born from 1987 through 1989 or in 1991 and 1992 to residents of St Louis with clinical data from the 4 neonatal intensive care units in the St Louis area; we then compared neonatal mortality during 2 periods, one before and one after the FDA's approval of surfactant for clinical use (1987 through 1989 and 1991 through 1992). RESULTS: The use of surfactant increased by a factor of 10 between 1987 through 1989 and 1991 through 1992. The neonatal mortality rate among all very-low-birthweight infants decreased 17%, from 220.3 deaths per 1,000 very-low-birthweight babies born alive (in 1987 through 1989) to 183.9 per 1,000 (in 1991 through 1992; p = 0.07). This decrease was due to a 41% reduction in the mortality rate among white newborns with very low birthweights (from 261.5 per 1,000 to 155.5 per 1,000; p = 0.003). In contrast, among black infants, the mortality rate for very-low-birthweight infants did not change significantly (195.6 per 1,000 and 196.8 per 1,000). The relative risk of death among black newborns with very low birthweights as compared with white newborns with similar weights was 0.7 from 1987 through 1989 and 1.3 from 1991 through 1992 (p = 0.02). The differences in mortality were not explained by differences in access to surfactant therapy, by differences in mortality between black and white infants who received surfactant, or by differences in the use of antenatal corticosteroid therapy. CONCLUSIONS: After surfactant therapy for RDS became generally available, neonatal mortality improved more for white than for black infants with very low birthweights.

**Aerosolized Surfactant in Adults with Sepsis-Induced Acute Respiratory Distress Syndrome**—A Anzueto, RP Baughman, KK Guntupalli, JG Weg, HP Wiedemann, AA Raventos, F Lemaire, W Long, DS Zaccardelli, EN Pattishall for the Exosurf Acute Respiratory Distress Syndrome Sepsis Study Group. N Engl J Med 1996; 334(22):1417-1421

BACKGROUND: Patients with acute respiratory distress syndrome (ARDS) have a deficiency of surfactant. Surfactant replacement improves physiologic function in such patients, and preliminary data suggest that it may improve survival. METHODS: We conducted a prospective, multicenter, double-blind, randomized, placebo-controlled trial involving 725 patients with sepsis-induced ARDS. Patients were stratified according to the risk of death at base line (indicated by their score on the Acute Physiologic and Chronic Health Evaluation [APACHE III] index) and randomly assigned to receive either continuously administered synthetic surfactant (13.5 mg of dipalmitoylphosphatidylcholine per milliliter; 364 patients) or placebo (0.45% saline; 361 patients) in aerosolized form for up to 5 days. RESULTS: The demographic and physiologic characteristics of the 2 treatment groups were similar at base line. The mean (± SD) age was 50 ± 17 years in the surfactant group and 53 ± 18 years in the placebo group, and the mean APACHE III scores at randomization were 70.4 ± 25 and 70.5 ± 25, respectively. Hemodynamic measures, measures of oxygenation, duration of mechanical ventilation, and length of stay in the intensive care unit did not differ significantly in the 2 groups. Survival at 30 days was 60% for both groups. Survival was similar in the groups when analyzed according to APACHE III score, cause of death, time of onset and severity of ARDS, presence or absence of documented sepsis, underlying disease, whether or not there was a do-not-resuscitate order, and medical center. Increased secretions were significantly more frequent in the surfactant group, the rates of other complications were similar in the 2 groups. CONCLUSIONS: The continuous administration of aerosolized synthetic surfactant to patients with sepsis-induced ARDS had no significant effect on 30-day survival, length of stay in the intensive care unit, duration of mechanical ventilation, or physiologic function. *See the related editorial:* ***The Acute Respiratory Distress Syndrome*** *—MA Matthay. N Engl J Med 1996;334(22):1469-1470.*

**Histopathologic and Microbiologic Aspects of Ventilator-Associated Pneumonia**—N Fabregas, A Torres, M El-Ebiary, J Ramirez, C Hernandez, J González, JP de la Bellacasa, J de Anta, R Rodriguez-Roisin. Anesthesiology 1996;84(4): 760-771.

BACKGROUND: The relationship between microbiology and histology in patients with ventilator-associated pneumonia has been sparsely described. METHODS: Twenty-five patients who died in the intensive care unit after their lungs had been mechanically ventilated for 72 hours were studied. Twenty of the 25 died with clinical suspicion of pulmonary infection. A total of 375 immediate postmortem pulmonary biopsies were obtained after death and processed for quantitative microbiology and histology. Four evolutionary stages of pneumonia were defined: early, intermediate, advanced, and resolution. RESULTS: At least one specimen with histologic evidence of pneumonia was found in all but 2 patients (92%). Histologic pneumonia was a widespread and frequent process (46% of biopsies examined) involving predominantly the lower lobes (55% of all biopsies with pneumonia) and showing different histopathologic stages of progression coexisting in the same lung lobes. Lung cultures were frequently polymicrobial (149 of 375, 40% of the pulmonary biopsy cultures, and 20 of 25, 80% of the cases) and not always yielding the same pathogen (19 micro-organisms) when comparing one lung to the other. Histopathology and microbiologic biopsy cultures showed a weak relationship (28% and 49% of species had counts $\geq 10^3$ cfu/g in samples without pneumonia from patients with and without prior antibiotic treatment, respectively). Histopathologic evolutionary stages were not associated with any differences in quantitative culture results of pulmonary biopsies, independently of prior administration of antibiotics. Higher bacterial concentrations of biopsy cultures were associated with the absence of prior antibiotic treatment. CONCLUSIONS: Ventilator-associated pneumonia is a frequent diffuse and polymicrobial process showing different coexisting degrees of evolution and involving preferentially the lower lobes. Microbiology and histology can be dissociated even in the absence of prior antibiotic treatment. Lung histology appears more reliable than bacteriology as a diagnostic reference test. *See the related editorial:* ***Nosocomial Infection in the Critically Ill: The Lung as a Target Organ*** *—JJ Rouby. Anesthesiology 1996;84(4):757-759.*

**Lung Volume Reduction Surgery for Emphysema**—M Brenner, R Yusen, R McKenna Jr, F Sciurba, AF Gelb, R Fischel, J Swain, JC Chen, F Kafie, SS Lefrak. Chest 1996;110(1):205.

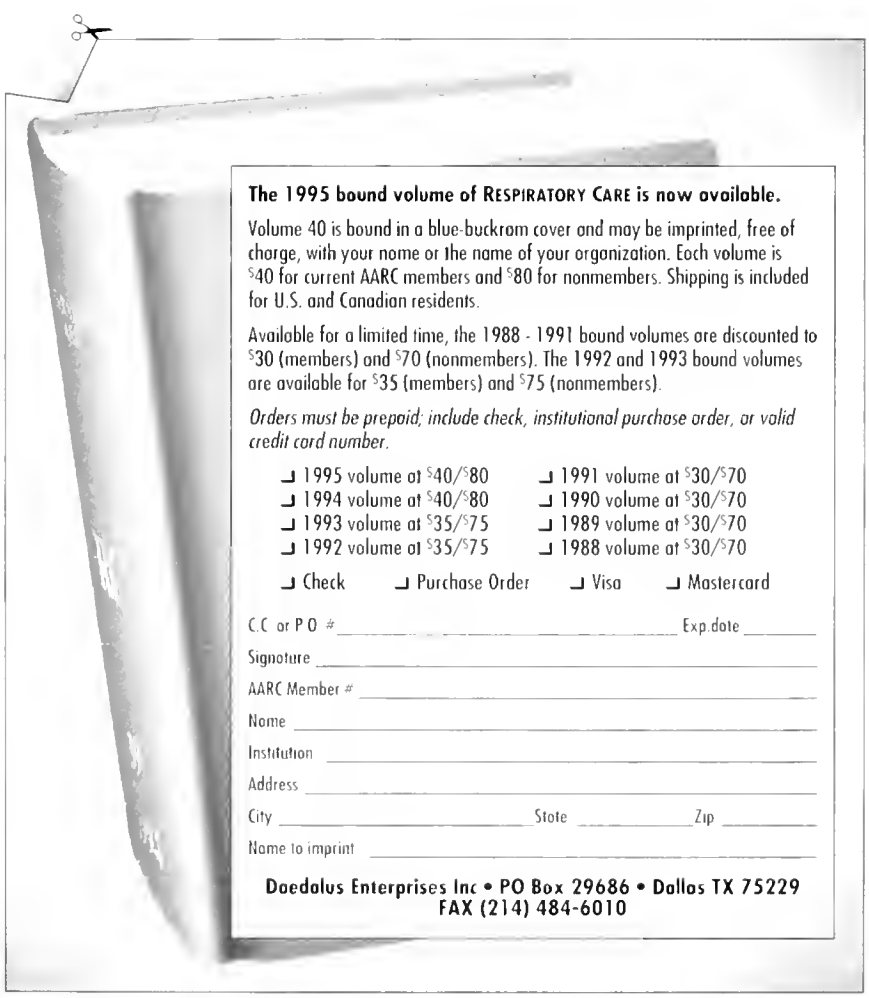
There has been dramatic resurgence of interest in surgical treatment of emphysema, particularly "lung volume reduction" procedures. Recent studies have demonstrated improvements in pulmonary function, lung mechanics, exercise tolerance, and quality of life in selected patients following volume reduction procedures. However, considerable uncertainty remains regarding overall benefit, optimal patient selection, operative techniques, and duration of response. This review summarizes current approaches to lung volume reduction surgery, available clinical outcome information, selection criteria, and physiologic mechanisms of response, and discusses the potential role for surgical volume reduction in treatment of emphysema. Recent data appear to support the efficacy of bilateral staple lung volume reduction surgery in patients with severe symptomatic heterogeneously distributed emphysema. Further studies will be needed to determine relative value of different operative techniques and benefit in patients with other clinical presentations.

**Contribution of Lung and Chest Wall Mechanics Following Emphysema Resection**—AF Gelb, RJ McKenna Jr, M Brenner, R Fischel, A Baydur, N Zamel. Chest 1996;110(1):11.

OBJECTIVE: To determine the contributions of (1) chest wall ($P_{cw}$) and (2) lung elastic recoil pressure ($P_L$) to (3) total elastic recoil pressure exerted by the respiratory system ($P_{rs}$) in 18 patients (12 men) aged 66 ± 6 years (mean ± 1 SD) with severe emphysema who underwent video-assisted thoracoscopic bilateral lung volume reduction surgery under paralyzed (vecuronium) general anesthesia (isoflurane). DESIGN: We measured preoperative and 6-week postoperative lung function studies, and intraoperative inspiratory lung conductance ($G_L$), $P_L$, $P_{cw}$, and $P_{rs}$ (cm $H_2O$) at end-expiratory lung volume (EELV), EELV plus 0.60 ± 0.01 L, and EELV plus 1.15 ± 0.01 L. All values are mean ± SEM. RESULTS: Preoperative vs postoperative FVC was 1.9 ± 0.1 L vs 2.3 ± 0.1 L ($p = 0.03$); $FEV_1$ was 0.6 ± 0.1 L vs 0.9 ± 0.1 L ($p < 0.02$); total lung capacity was 7.4 ± 0.4 L vs 5.9 ± 0.3 L ($p < 0.001$); functional residual capacity was 5.7 ± 0.4 L vs 4.4 ± 0.2 L ($p = 0.001$). At EELV preoperative vs postoperative, $P_L$ was 0.0 ± 0.3 vs 1.1 ± 0.05 ($p = 0.04$), $P_{cw}$ was 5.0 ± 0.7 vs 2.4 ± 0.9 ($p = 0.02$), and $P_{rs}$ was 5.0 ± 0.8 vs 3.5 ± 0.7 ($p = 0.08$). At EELV plus 0.60 L, $P_L$ was 3.2 ± 0.6 vs 6.1 ± 0.9 ($p < 0.001$), $P_{cw}$ was 8.8 ± 0.8 vs 7.0 ± 0.9 ($p = 0.12$), and $P_{rs}$ was 12.0 ± 0.8 vs 13.1 ± 0.7 ($p = 0.80$). At EELV plus 1.15 L, $P_L$ was 6.8 ± 0.9 vs 10.3 ± 1.1 ($p < 0.001$), $P_{cw}$ was 13.5 ± 1.0 vs 11.2 ± 1.2 ($p = 0.12$), and $P_{rs}$ was 20 ± 1.2 vs 21.5 ± 1.0 ($p = 0.93$). At EELV plus 0.60 L, $G_L$ was 0.09 ± 0.00 L · s$^{-1}$ · cm $H_2O^{-1}$ vs 0.16 ± 0.01 ($p < 0.01$). At EELV plus 1.15 L, $G_L$ was 0.12 ± 0.01 vs 0.21 ± 0.03 ($p < 0.05$) with similar preoperative vs postoperative $G_L/P_L$ slopes. CONCLUSION: The increase in $P_L$ and decrease in $P_{cw}$ following LVRS for emphysema may be responsible for the increase in spirometry and airway conductance.

**Mechanisms of Relief of Exertional Breathlessness Following Unilateral Bullectomy and Lung Volume Reduction Surgery in Emphysema**—DE O'Donnell, KA Webb, JC Bertley, LKL Chau, AA Conlan. Chest 1996;110(1):18.

OBJECTIVE: To explore mechanisms of relief of exertional breathlessness following surgery to reduce thoracic gas volume in patients with emphysema. MATERIALS & METHODS: We studied 8 patients with emphysema ($FEV_1$ = 39 ± 3% predicted, residual volume [RV] = 234 ± 12% predicted; mean ± SEM) who were severely breathless despite optimal pharmacotherapy and who underwent unilateral bullectomy for giant bullae (greater than one third hemithorax); 4 of these also had ipsilateral lung reduction (pneumectomy). Pulmonary function and cycle exercise performance (n = 6) were evaluated before and 13 ± 3 weeks after surgery. Chronic breathlessness was measured with the Baseline Dyspnea Index and the Medical Research Council dyspnea scale. Exertional breathlessness was measured using Borg ratings at a standardized work rate (BorgSTD). RESULTS: $FEV_1$, FVC, and maximal inspiratory pressures increased postsurgery by 29 ± 7% ($p < 0.05$), 24 ± 10% ($p = 0.06$), and 39 ± 12% ($p < 0.01$), respectively. Plethysmographic total lung capacity, RV, and functional residual capacity fell by 14 ± 2%, 30 ± 4%, and 18 ± 3%, respectively ($p < 0.001$). All measures of chronic breathlessness improved significantly ($p < 0.05$). During exercise at a standardized work rate, BorgSTD fell 45% ($p < 0.05$), end-expiratory lung volume (EELV) fell 22% ($p < 0.01$), and breathing frequency (F) fell 25% ($p = 0.08$). By multiple stepwise regression analysis, 99% ($p = 0.007$) of the variance in symptom relief (ΔBorgSTD) was explained by the combination of decreased ratio of the end-expiratory lung volume to total lung capacity, decreased F, and diminished mechanical constraints on tidal volume (tidal volume to

vital capacity ratio). CONCLUSION: Reduced exertional breathlessness at a given workload after volume reduction surgery was attributed to a combination of reduced thoracic hyperinflation, reduced F, and reduced mechanical constraints on lung volume expansion.

**Lung Volume Reduction in Patients with Severe Diffuse Emphysema: A Retrospective Study**—C Roué, H Mal, C Sleiman, M Fournier, J Duchatelle, P Baldeyrou, R Pariente. Chest 1996;110(1):28.

BACKGROUND: For most authors, surgery of emphysema is restricted to resection of large bullae, whereas resection of small bullae or lung volume reduction is generally considered to have poor results. OBJECTIVE: To report our experience of lung volume reduction in patients with severe emphysema without large bullae. PATIENTS: Thirteen patients were operated on from 1982 to 1992. Before surgery, they all had severe diffuse emphysema with a dyspnea grade 4 or 5 and mean $FEV_1$ values of 18 ± 5% of predicted. Seven patients had a $P_{aCO_2}$ greater than 42 mm Hg. On radiologic evaluation, they had either small bullae or, most often, areas of destroyed lung. INTERVENTION: The surgical procedure was unilateral in 11 patients and bilateral in 2. MEASUREMENTS & RESULTS: Postoperative assessment included dyspnea grading, $FEV_1$ measurements, and blood gas analysis followed at 6- to 12-month intervals. There was no perioperative mortality and the morbidity was limited. At 6, 12, 18, 24, and 36 months postoperatively, a symptomatic improvement was observed in 92%, 85%, 54%, 31%, and 31% of the patients, respectively, with $FEV_1$ increasing by at least 20% in 92%, 46%, 46%, 31%, and 24% of the patients, respectively. CONCLUSION: Our data show that lung volume reduction may result in symptomatic and spirometric improvement in patients with severe emphysema without large bullae.

*The editorial:* ***Lung Volume Reduction: A Breath of Fresh Air?****—AG Little. Chest 1996;110(1)2-3 relates to the previous 4 abstracts.*

**Effects of Organizational Change in the Medical Intensive Care Unit of a Teaching Hospital: A Comparison of 'Open' and 'Closed' Formats**—SS Carson, C Stocking, T Podsadecki, J Christenson, A Pohlman, S MacRae, J Jordan, H Humphrey, M Siegler, J Hall. JAMA 1996;276(4):322.

OBJECTIVE: To compare the effects of change from an open to a closed intensive care unit (ICU) format on clinical outcomes, resource utilization, teaching, and perceptions regarding quality of care. DESIGN: Prospective cohort study; prospective economic evaluation. SETTING: Medical ICU at a university-based tertiary care center. For the open ICU, primary admitting physicians direct care of patients with input from critical care specialists via consultation. For the closed ICU, critical care specialists direct patient care. PATIENTS: Consecutive samples of 124 patients admitted under an open ICU format and 121 patients admitted after changing to a closed ICU format. Readmissions were excluded. MAIN OUTCOME MEASURES: Comparison of hospital mortality with mortality predicted by the Acute Physiology and Chronic Health Evaluation II (APACHE II) system; duration of mechanical ventilation; length of stay; patient charges for radiology, laboratory, and pharmacy departments; vascular catheter use; number of interruptions of formal teaching rounds; and perceptions of patients, families, physicians, and nurses regarding quality of care and ICU function. RESULTS: Mean ± SD APACHE II scores were 15.4 ± 8.3 in the open ICU and 20.6 ± 8.6 in the closed ICU ($p = 0.001$). In the closed ICU, the ratio of actual mortality (31.4%) to predicted mortality (40.1%) was 0.78. In the open ICU, the ratio of actual mortality (22.6%) to predicted mortality (25.2%) was 0.90. Mean length of stay for survivors in the open ICU was 3.9 days, and mean length of stay for survivors in the closed ICU was 3.7 days ($p = 0.79$). There were no significant differences between periods in patient charges for radiology, laboratory, or pharmacy resources. Nurses were more likely to say that they were very confident in the clinical judgment of the physician primarily responsible for patient care in the closed ICU compared with the open ICU (41% vs 7%; $p < 0.01$), and nurses were the group most supportive of changing to a closed ICU format before and after the study. CONCLUSIONS: Based on comparison of actual to predicted mortality, changing from an open to a closed ICU format improved clinical outcome. Although patients in the closed ICU had greater severity of illness, resource utilization did not increase.

**Double-Blind Placebo-Controlled Study of the Hyperventilation Provocation Test and the Validity of the Hyperventilation Syndrome**—HK Hornsveld, B Garssen, MJC Fiedeldij Dop, PI van Spiegel, JCJM de Haes. Lancet 1996; 348:154.

BACKGROUND: Hyperventilation syndrome (HVS) describes a set of somatic and psychological symptoms thought to result from episodic or chronic hyperventilation. Recognition of symptoms during the hyperventilation provocation test (HVPT) is the most widely used criterion for diagnosis of HVS. We have investigated the validity of the HVPT and of the concept of HVS. METHODS: In a randomized, double-blind, crossover design, the ability of 115 patients with suspected HVS to recognize symptoms during the HVPT was compared with the ability to recognize symptoms during a placebo test (isocapnic overbreathing, with carbon dioxide levels maintained by manual titration). Thirty patients who had positive results on the HVPT underwent ambulatory transcutaneous monitoring of $P_{tCO_2}$ to ascertain whether they hyperventilated during spontaneous symptom attacks. FINDINGS: Of the 115 patients who underwent the HVPT and the placebo test, 85 (74%) reported symptom recognition during the HVPT (positive diagnosis HVS). Of that subset, 56 were also positive on the placebo test (false-positive), and 29 were negative on the placebo test (true-positive). False-positive and true-positive patients did not differ in symptom profile or in physiological variables. During ambulatory monitoring (15 true-positive, 15 false-positive) 22 attacks were registered. Transcutaneous end-tidal $P_{tCO_2}$ decreased during only 7. The decreases were slight and apparently followed the onset of the attack, which suggests that hyperventilation is a consequence rather than a cause of the attack. There were no apparent differences between false-positive and true-positive patients. INTERPRETATION: The HVPT is invalid as a diagnostic test for HVS. Hyperventilation seems a negligible factor in the experience of spontaneous symptoms. The term HVS should be avoided.

**UK Collaborative Randomized Trial of Neonatal Extracorporeal Membrane Oxygenation**—UK Collaborative ECMO Trial Group. Lancet 1996; 348:75.

BACKGROUND: Extracorporeal membrane oxygenation (ECMO) is a complex and expensive technology that can be used to provide temporary support during respiratory failure. Its value for mature newborn infants is controversial because of varying interpretation of the available evidence. We undertook a collaborative trial throughout the UK to assess whether a policy of referral for ECMO has a beneficial effect on survival to 1 year without severe disability in comparison with conventional management. METHODS: Between 1993 and 1995, 185 mature (gestational age at birth ≥ 35 weeks, birthweight ≥ 2 kg) newborn infants with severe respiratory failure (oxygenation index ≥ 40) were enrolled from 55 hospitals in a randomized comparison of either referral to 1 of 5 specialist centers for consideration of ECMO or continued intensive conventional management at the original hospital. The most common diagnoses were persistent pulmonary hypertension due to meconium aspiration, congenital diaphragmatic hernia, isolated persistent fetal circulation, sepsis, and idiopathic respiratory distress syndrome. Of the infants allocated ECMO, 84% received this support. Recruitment to the trial was stopped early (November 1995) by the trial steering committee on the advice of the independent data-monitoring committee, because the data accumulated showed a clear advantage with ECMO. 124 children were enrolled before December 1994, those who survived to 1 year of age have undergone neurological assessment at that age (by 1 of 3 developmental paediatricians unaware of treatment allocation). FINDINGS: Overall, 81 (44%) infants died before leaving hospital, and 2 are known to

have died later. Death rates differed between the 2 trial groups, 30 of 93 infants allocated ECMO died compared with 54 of 92 allocated conventional care. The relative risk was 0.55 (95% CI 0.39-0.77; p = 0.0005), which is equivalent to 1 extra survivor for every 3 to 4 infants allocated ECMO. The difference in survival applied irrespective of the primary diagnosis, disease severity, and type of referral centre. The benefit of ECMO was also found for the primary outcome measure of death or disability at 1 year (among 124 children enrolled before December 1994). One child in each group has severe disability (overall Griffiths' developmental quotient < 50, or untestable), and 16 (10 ECMO, 6 conventional management) have impairments with a lesser degree of disability. INTERPRETATION: These preliminary results demonstrate the clinical effectiveness of a well-staffed and organized neonatal ECMO service. ECMO support should be actively considered for neonates with severe but potentially reversible respiratory failure. *See the related commentary:* ***Neonatal Extracorporeal Membrane Oxygenation—A Bridging Technique****– RF Soll, Lancet 1996;348:70-71.*

**Use of Racemic Epinephrine, Dexamethasone, and Mist in the Outpatient Management of Croup**— NC Kunkel, MD Baker. Pediatr Emerg Care 1996;12(3):156.

This study aims to determine whether a subpopulation of children with croup, given mist and dexamethasone, can be treated with nebulized racemic epinephrine and safely discharged after observation in the emergency department. A prospective study was designed, enrolling children aged 3 months to 6 years with a clinical diagnosis of croup. Croup scores were assigned on arrival, after 30 minutes of saline mist, and 30, 120, and 240 minutes after nebulized racemic epinephrine. All children received mist; those with a croup score >3 after mist were given nebulized racemic epinephrine. All patients received intramuscular dexamethasone. Patients were discharged if they were significantly improved after 4 hours of observation. Phone follow-up occurred 24 to 48 hours after discharge. Sixty children received racemic epinephrine for croup. The median croup score on arrival was 5, and there was no difference in arrival croup score by disposition. The 2-hour croup score was significantly higher for admitted patients ($p < 0.05$ by the Mann-Whitney *U* test). Forty children (66%) were discharged after nebulized racemic epinephrine and 4 hours of observation. No patients returned to the emergency department within 24 hours for further treatment. Two patients could not be contacted. The 95% confidence interval for 0/38 patients with a negative outcome is (0-9.3%). We conclude that children with croup treated with dexamethasone and mist, receiving 1 nebulized racemic epinephrine treatment, can be discharged after a 4-hour period of observation if they appear clinically well to an experienced physician, and if close follow-up can be established.

**Can Physical Activity Minimize Weight Gain in Women after Smoking Cessation?**—I Kawachi, RJ Troisi, AG Rotnitzky, EH Coakley, GA Colditz. Am J Public Health 1996;86(7):999.

OBJECTIVES: The purpose of this study was to examine prospectively whether exercise can modify weight gain after smoking cessation in women. METHODS: Data were analyzed from a 2-year follow-up period (1986-1988) in the Nurses' Health Study, an ongoing cohort of 121,700 U.S. women aged 40 to 75 in 1986. RESULTS: The average weight gain over 2 years was 3.0 kg in the 1,474 women who stopped smoking, and 0.6 kg among the 7,832 women who continued smoking. Among women smoking 1 to 24 cigarettes per day, those who quit without changing their levels of exercise gained an average of 2.3 kg more (95% confidence interval [CI] = 1.9, 2.6) than women who continued smoking. Women who quit *and* increased exercise by between 8 to 16 MET-hours (the work metabolic rate divided by the resting metabolic rate) per week gained 1.8 kg (95% CI = 1.0, 2.5), and the excess weight gain was only 1.3 kg (95% CI = 0.7, 1.9) in women who increased exercise by more than 16 MET-hours per week. CONCLUSIONS: Smoking cessation is associated with a net excess weight gain of about 2.4 kg in middle-aged women. However, this weight gain is minimized if smoking cessation is accompanied by a moderate increase in the level of physical activity.

**Influences of Cardiorespiratory Fitness and Other Precursors on Cardiovascular Disease and All-Cause Mortality in Men and Women**— SN Blair, JB Kampert, HW Kohl III, CE Barlow, CA Macera, RS Paffenbarger Jr, LW Gibbons. JAMA 1996;276(3):205.

OBJECTIVE: To quantify the relation of cardiorespiratory fitness to cardiovascular disease (CVD) mortality and to all-cause mortality within strata of other personal characteristics that predispose to early mortality. DESIGN: Observational cohort study. We calculated CVD and all-cause death rates for low (least fit 20%), moderate (next 40%), and high (most fit 40%) fitness categories by strata of smoking habit, cholesterol level, blood

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pressure, and health status. SETTING: Preventive medicine clinic. STUDY PARTICIPANTS: Participants were 25,341 men and 7,080 women who completed preventive medical examinations, including a maximal exercise test. MAIN OUTCOME MEASURES: Cardiovascular disease and all-cause mortality. RESULTS: There were 601 deaths during 211,996 man-years of follow-up, and 89 deaths during 52,982 woman-years of follow-up. Independent predictors of mortality among men, with adjusted relative risks (RRs) and 95% confidence intervals (CIs), were low fitness (RR, 1.52; 95% CI, 1.28-1.82), smoking (RR, 1.65; 95% CI, 1.39-1.97), abnormal electrocardiogram (RR, 1.64, 95% CI, 1.34-2.01), chronic illness (RR, 1.63; 95% CI, 1.37-1.95), increased cholesterol level (RR, 1.34, 95% CI, 1.13-1.59), and elevated systolic blood pressure (RR, 1.34; 95% CI, 1.13-1.59). The only statistically significant independent predictors of mortality in women were low fitness (RR, 2.10; 95% CI, 1.36-3.21) and smoking (RR, 1.99; 95% CI, 1.25-3.17). Inverse gradients were seen for mortality across fitness categories within strata of other mortality predictors for both sexes. Fit persons with any combination of smoking, elevated blood pressure, or elevated cholesterol level had lower adjusted death rates than low-fit persons with none of these characteristics. CONCLUSIONS: Low fitness is an important precursor of mortality. The protective effect of fitness held for smokers and nonsmokers, those with and without elevated cholesterol levels or elevated blood pressure, and unhealthy and healthy persons. Moderate fitness seems to protect against the influence of these other predictors on mortality. Physicians should encourage sedentary patients to become physically active and thereby reduce the risk of premature mortality.

**Physical Activity and Cardiovascular Health**—NIH Consensus Development Panel on Physical Activity and Cardiovascular Health. JAMA 1996;276(3):241.

OBJECTIVE: To provide physicians and the general public with a responsible assessment of the relationship between physical activity and cardiovascular health. PARTICIPANTS: A nonfederal, nonadvocate, 13-member panel representing the fields of cardiology, psychology, exercise physiology, nutrition, pediatrics, public health, and epidemiology. In addition, 27 experts in cardiology, psychology, epidemiology, exercise physiology, geriatrics, nutrition, pediatrics, public health, and sports medicine presented data to the panel and a conference audience of 600 during a 2-day public session. Questions and statements from conference attendees were considered during the open session. Closed deliberations by the panel occurred during the remainder of the second day and the morning of the third day. EVIDENCE: The literature was searched through MEDLINE, and an extensive bibliography of references was provided to the panel and the conference audience. Experts prepared abstracts with relevant citations from the literature. Scientific evidence was given precedence over clinical anecdotal experience. CONSENSUS PROCESS: The panel, answering predefined questions, developed their conclusions based on the scientific evidence presented in open forum and the scientific literature. CONSENSUS STATEMENT: The panel composed a draft statement that was read in its entirety and circulated to the experts and the audience for comment. Thereafter, the panel resolved conflicting recommendations and released a revised statement at the end of the conference. The panel finalized the revisions within a few weeks after the conference. CONCLUSIONS: All Americans should engage in regular physical activity at a level appropriate to their capacity, needs, and interest. Children and adults alike should set a goal of accumulating at least 30 minutes of moderate-intensity physical activity on most, and preferably all, days of the week. Most Americans have little or no physical activity in their daily lives, and accumulating evidence indicates that physical inactivity is a major risk factor for cardiovascular disease. However, moderate levels of physical activity confer significant health benefits. Even those who currently meet these daily standards may derive additional health and fitness benefits by becoming more physically active or including more vigorous activity. For those with known cardiovascular disease, cardiac rehabilitation programs that combine physical activity with reduction in other risk factors should be more widely used.

**Early versus Late Identification of Infants at High Risk of Developing Moderate to Severe Bronchopulmonary Dysplasia**—HJ Rozycki, L Narla. Pediatr Pulmonol 1996;21:345.

We developed a simple method to identify neonates at high risk of bronchopulmonary dysplasia (BPD) and determined whether early (8 hours) and late (14 days) risk assessment is equally useful. A retrospective cohort design was utilized of subjects enrolled in multi-dose surfactant trials to develop each risk identification model. Prospective testing of the late 14-day model was done to determine accuracy. The primary outcome variable (moderate to severe BPD) was defined as the need for oxygen and mechanical ventilation beyond 28 days of life and significant chest X-ray changes. Variables were screened for inclusion in the models by univariate and multiple regression analysis of data available at 14 days or 8 hours of life, converted to yes-no variables by the use of receiver-operator curves; the final model was based on those variables that gave the highest sensitivity and specificity for identifying BPD risk. Thirty-eight out of 116 of the 14-day model subjects developed BPD. The 14-day model [$F_{IO_2} \geq 0.30$ and ventilation index (defined as 10,000/peak pressure · rate × $P_{CO_2}$) < 0.510 (or < 0.800 if previously septic)] had a sensitivity of 82% and specificity of 89%. It accurately identified 83% of cases (51/61) during a 1-year prospective test. The positive predictive value was 81% and negative predictive value 88%. Forty-four of the 698 early 8-hour model subjects developed BPD. The 8-hour model [gestational age < 31 weeks, 5-minute Apgar < 9, ventilator rate > 23 breaths/min, and ventilation index < 0.895] had a sensitivity of 73%, specificity of 83%, negative predictive value of 98% but positive predictive value of only 22%. These observations indicated that clinical data can create an accurate and simple model to classify infants into high- or low-risk groups for BPD. Using such models very early in life (eg, at 8 hours) may lead to a high number of false-positive identifications.

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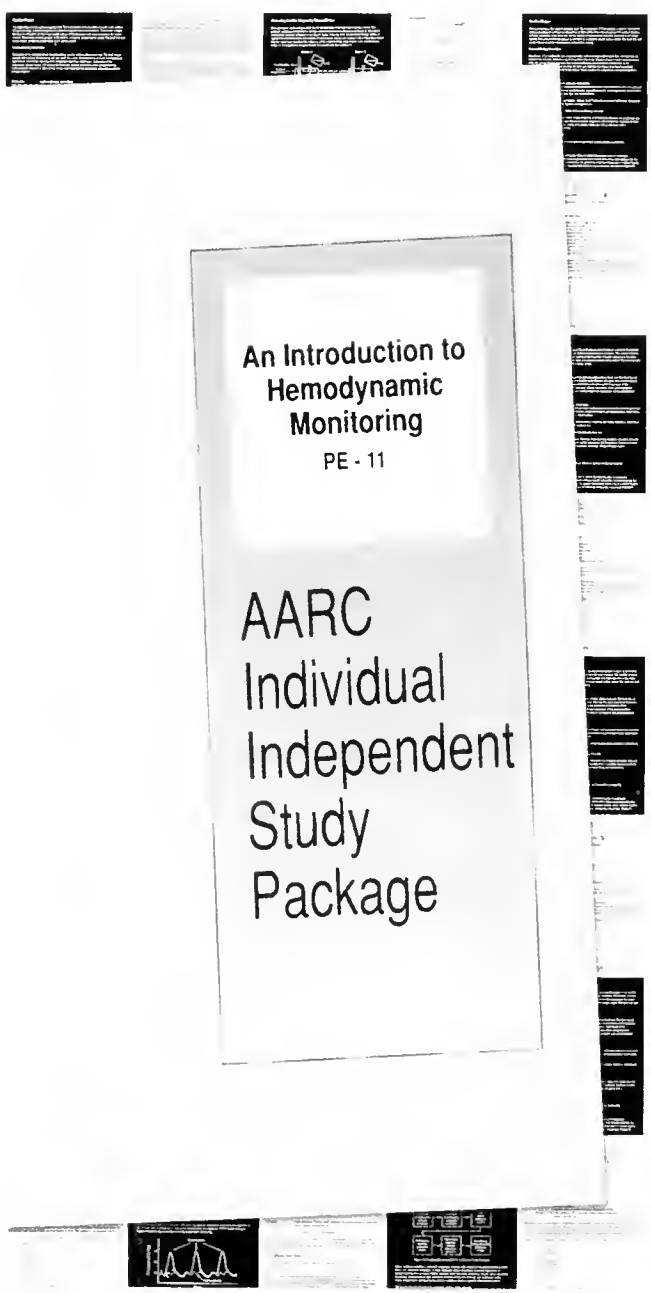


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**Item SC2**

# Accuracy and Precision of a Point-of-Care Blood Gas Analyzer Incorporating Optodes

Neil R MacIntyre MD, Brian Lawlor RRT, Donna Carstens MD, and Dennis Yetsko RRT

**BACKGROUND: A new generation of blood gas analyzers has appeared, and these analyzers are said to be easy to use, portable, battery-powered, and potentially less expensive than conventional systems. These systems allow for point-of-care analysis in emergency rooms, intensive care units, outpatient settings, and transport vehicles. However, the accuracy and precision of these analyzers must be established before they can be used interchangeably with standard laboratory analyzers. We, thus, undertook an evaluation of one such system, the OPTI 1 (AVL Scientific Corporation, Roswell GA). METHODS: Two types of evaluation were performed. The first was an analysis of paired-sample measurements on 114 randomly selected patient blood samples using the new system and our standard analyzer. The second analysis consisted of using standard reference material to assess reproducibility (precision) of the analyzer over a 20-day period. RESULTS: In the paired-sample analysis, the correlation coefficients for the values determined by the two systems showed a significant relationship (r = 0.962 for pH, r = 0.9955 for $P_{CO_2}$, and r = 0.9829 for $P_{O_2}$). Using the means and standard deviations of the observed differences, in conjunction with Clinical Laboratory Improvement Amendment (CLIA) standards and the 1995 College of American Pathology Blood Gas Survey Reporting data, we calculated that the observed range of differences is within "interchangeability" ranges. CONCLUSION: We conclude that the OPTI 1 analyzer has adequate accuracy and precision for use in the clinical arena.** [Respir Care 1996;41(9):800-804]

## Background

The ability to measure pH, $P_{O_2}$, and $P_{CO_2}$ (so-called blood gases) has been a cornerstone of diagnosis and monitoring in a variety of cardiorespiratory disorders.[1] Standard laboratory analyzers usually utilize 3 separate electrodes to determine these values in blood samples. However, standard analyzers are expensive and require frequent calibration and dedicated personnel for proper operation. Because of this, they are usually located in central hospital laboratories, and samples must be brought for analysis from the point of care by messengers or tube systems.

In recent years, blood gas analyzers have been developed that are potentially less expensive and easy for nontechnical personnel to calibrate and use.[2-4] Moreover, these systems are lightweight, have a short warm-up period, and can be battery powered—features that allow for point-of-care (POC) testing because the analyzer can be brought to the patient in the emergency room, intensive care unit (ICU), physician's office, or transport vehicle. Rapid, potentially less expensive blood gas analysis can therefore be made widely available. Examples of currently available POC devices are listed in Table 1.

The authors are associated with Respiratory Care Services, Duke University Medical Center, Durham, North Carolina.

The authors have no direct financial interest in the products evaluated, however, Dr MacIntyre is a consultant to AVL Scientific Corp.

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Table 1. Characteristics of Point-of-Care Blood Gas-pH Analyzers Based on Manufacturer's Specifications

| | AVL OPTI 1 | Diametrics IRMA | PPG Biomedical Stat Pal 2 | i-Stat |
|---|---|---|---|---|
| Sample size | 80 μL | 200 μL | 800 μL | 90 μl |
| Analysis time | 90 s | 90 s | 60 s | 120 s |
| Range of measurements | | | | |
| pH (units) | 6.9-7.7 | 6.8-7.8 | 6.8-7.8 | 6.8-8 |
| $P_{CO_2}$ (torr) | 10-120 | 4-150 | 1-99 | 10-100 |
| $P_{O_2}$ (torr) | 20-500 | 20-500 | 0-600 | 5-800 |
| Power supply | battery/AC | battery | battery | battery |
| Sensor | fluorescence | electrochemical, thick film | electrochemical, thick film | microelectrodes, thick film |
| Patient samples per analysis package | 1 | 1 | 8, 15, 30 | 1 |

Because accuracy of blood gas results is obviously important, point-of-care analyzers must be shown to be comparable to standard systems before widespread use can be recommended.[2] We undertook an assessment of one such system, the OPTI 1 (AVL Scientific Corp, Roswell GA). This particular system uses optodes (optical sensors using fluorescence properties of the testing material) to measure pH, $P_{O_2}$, and $P_{CO_2}$ in small samples.[5] This system incorporates a single-use sample chamber with sensors that have been subjected to a 6-point calibration routine by the manufacturer. Blood samples are drawn into this chamber and analyzed in approximately 90 seconds.

The goal of our study was to assess the accuracy and the precision of this analyzer. Accuracy and precision in whole blood were assessed by comparing the OPTI 1 analyzer results with results obtained from our standard laboratory analyzer (ABL-500, Radiometer, Copenhagen) on the same sample. Precision was further assessed by doing repeated measures on both a standard reference cassette and on aqueous control material over a 20-day period.

## Methods

On each day of the 20-day period, the OPTI 1 analyzer was subjected to the manufacturer's warm-up and quality control procedures, using optical simulators ("standard reference cassettes"). Accuracy and precision of the analyzer were assessed using whole blood, and precision was assessed using standard samples.

### Accuracy & Precision Using Whole Blood

Blood samples (2-3 mL) taken from hospitalized adult patients for clinical reasons were analyzed on both the OPTI 1 analyzer and on the standard laboratory analyzer. The laboratory analyzer was calibrated, maintained, and serviced according to manufacturer's specifications. Moreover, this analyzer was subject to Medicare-mandated quality control procedures (Clinical Laboratories Improvement Act, or CLIA)[6] and was part of the College of American Pathologists (CAP) proficiency program and certification process. Blood samples were delivered to the laboratory by a tube system from one of several intensive care units. After clearance of any visible air bubbles, split samples were run immediately through each analyzer in random sequence. A certified laboratory technician performed analysis on the standard analyzer. One of us (DC), a physician not formally trained in laboratory procedures, performed the analysis on the OPTI 1 system. Results for pH, $P_{O_2}$, and $P_{CO_2}$ from the two analyzers were then assessed by linear regression from which the slope, intercept, and correlation coefficient of the relationship were calculated. The mean and standard deviation (SD) of the differences between the paired results were also calculated.

### Precision Assessment Using Standard Samples

Precision was assessed using both a standard reference cassette (SRC) and an aqueous control solution. Two SRCs were used—one with optical characteristics simulating a blood sample with high values for $P_{O_2}$, $P_{CO_2}$, and pH, and one with characteristics simulating low values. These cassettes were analyzed each morning for 20 consecutive working days by a certified laboratory technician to establish reproducibility of the analyzer (ie, precision). Precision was expressed as the coefficient of variation (ie, SD/mean × 100) for the 20 samples). Two aqueous control samples were also tested each morning for 20 consecutive working days. These aqueous controls had either high or low values for $P_{O_2}$, $P_{CO_2}$, and pH. Precision was again expressed as the coefficient of variation (ie, SD/mean × 100) for the 20 samples.

## Results

### Accuracy & Precision Assessment Using Whole Blood

The results of the analysis of the 114 blood samples on both the OPTI 1 analyzer and the standard laboratory analyzer are

shown (Fig. 1). The correlation coefficients for $P_{O_2}$, $P_{CO_2}$, and pH were all high and ranged from 0.9692 to 0.9955. The slopes for all 3 measurements were close to 1.0 (0.96 to 1.03) and the y intercepts for all 3 measurements were close to zero. Table 2 lists the means and standard deviations of the differences for all paired samples of pH, $P_{O_2}$, and $P_{CO_2}$. In Figure 2, differences between values for the 3 variables determined by the 2 analyzers are plotted against the means of the values obtained (ie, Bland-Altman plots).

Table 2. Means and Standard Deviations of the Individual Differences in 114 Paired-Sample Blood Gas and pH Measurements Performed on the OPTI 1 and the ABL 500

| | |
|---|---|
| pH (units) | −0.010 ± 0.017 |
| $P_{CO_2}$ (torr) | 1.59 ± 1.44 |
| $P_{O_2}$ (torr) | −3.86 ± 4.98 |

## Precision Studies Using Standard Samples

The coefficients of variation (CV) for both the SRC sample and the aqueous control sample over the 20-day testing period are reported in Table 3.

Table 3. Coefficients of Variation (CV) for Repeated Measurements of Standard Reference Cassettes and Aqueous Controls (AC) on the OPTI 1 System

| | Mean | Standard Deviation | Coefficient of Variation |
|---|---|---|---|
| Standard Reference Cassettes (n = 20) | | | |
| pH | | | |
| Low | 7.100 | 0.001 | 0.014% |
| High | 7.570 | 0.001 | 0.013% |
| $P_{CO_2}$ | | | |
| Low | 20.0 | 0.11 | 0.55% |
| High | 70.1 | 0.12 | 0.17% |
| $P_{O_2}$ | | | |
| Low | 54.8 | 0.16 | 0.29% |
| High | 164.8 | 0.27 | 0.16% |
| Aqueous Controls (n = 20) | | | |
| pH | | | |
| Low | 7.127 | 0.008 | 0.12% |
| High | 7.392 | 0.011 | 0.15% |
| $P_{CO_2}$ | | | |
| Low | 47.64 | 0.911 | 1.93% |
| High | 77.93 | 1.74 | 2.23% |
| $P_{O_2}$ | | | |
| Low | 81.02 | 4.27 | 5.27% |
| High | 104.94 | 8.49 | 8.09% |

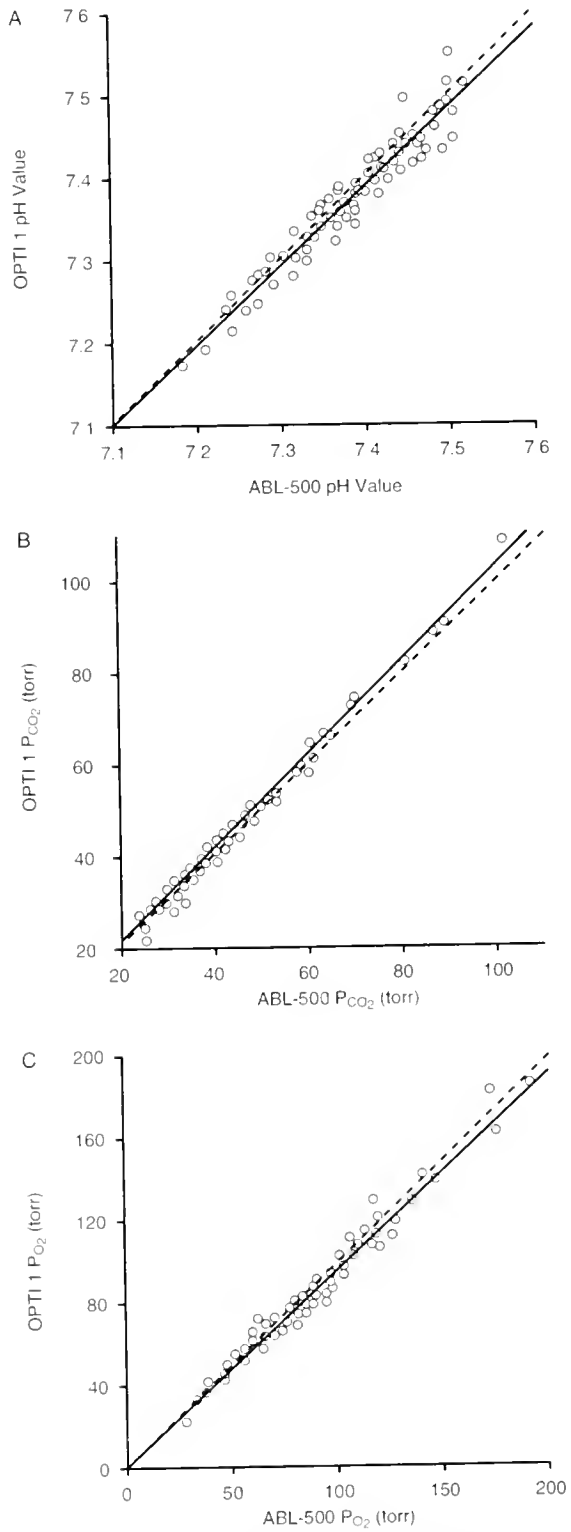


Fig. 1. Plot of values from analysis of 114 whole-blood samples by ABL-500 (horizontal axis) and the OPTI 1 (vertical axis) with —— = regression and - - - = identity line. A. pH determinations. Regression equation: OPTI 1 = 0.9643 ABL-500 + 0.2538 (r = 0.9692). B. $P_{CO_2}$ determinations. Regression equation: OPTI 1 = 1.0304 ABL-500 + 0.386 (r = 0.9955). C. $P_{O_2}$ determinations. Regression equation: OPTI 1 = 0.9707 ABL 500 − 1.387 (r = 0.9829).

## Discussion

One facet of assessment of analyzer performance is the measurement of accuracy and precision. Accuracy is usu-

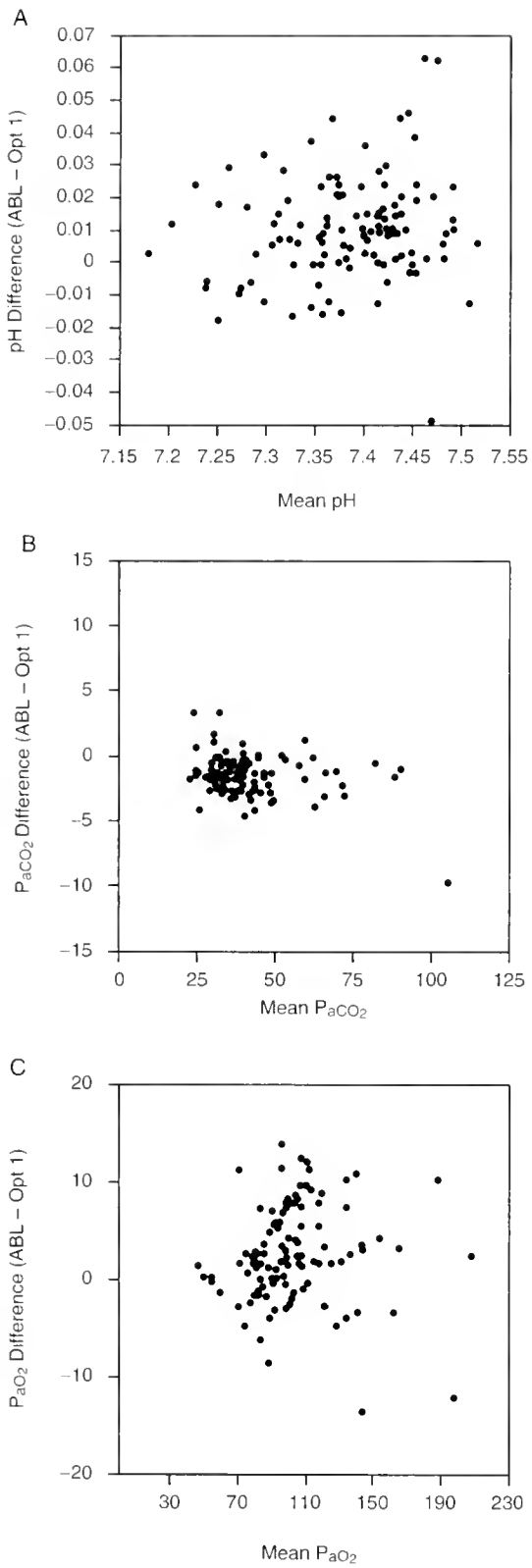


Fig. 2. Bland-Altman plot of values from analysis of 114 whole-blood samples by ABL-500 and OPTI 1. Differences between ABL-500 and OPTI 1 values (vertical axis) are plotted against means of ABL-500 and OPT 1 values (horizontal axis). A. pH. B. $P_{CO_2}$. C. $P_{O_2}$.

ally expressed as the difference between the analyzer's results and a gold standard. Precision reflects the stability or reproducibility of the analyzer and is usually expressed as the standard deviation or as the coefficient of variation (coefficient of variation = standard deviation/mean × 100) of repeated measurements.

In the present study, we assessed accuracy and precision of the OPTI 1 analyzer in several ways. Accuracy was assessed by comparing results of paired-sample measurements using the standard laboratory analyzer as the gold standard. Precision was assessed by determining both the variability of these paired-sample accuracy measurements and the reproducibility of measurements using a standard reference cassette and an aqueous control.

The important question, of course, is whether the results of these accuracy and precision determinations are sufficiently good to justify the use of the OPTI 1 analyzer in place of a standard analyzer. To address this, Bland and Altman[7] have suggested that if the range encompassed by the mean ± 2 SD of observed differences on paired measurements on the new and the standard analyzer is "not clinically important," then the 2 analyzers may be used interchangeably. Modifying this approach to define "clinically important" in the context of Medicare and the CLIA requirements for pH/blood-gas proficiency standards,[6] we used the following criteria for "interchangeability": Current Medicare CLIA proficiency standards[6] require that 80% of samples used for proficiency testing be within ± 0.04 units of a pH target, ± 5 torr (or 8%) of a $P_{CO_2}$ target, and ± 3 SD of a $P_{O_2}$ target derived from participating centers. If we substitute our standard analyzer results as these target values and use the observed mean ± 2 SD of the differences in measurements on the two systems (Table 2) with these criteria, we can conclude that the OPTI 1 analyzer and the standard analyzer are essentially interchangeable (Table 4). Supporting this conclusion is the fact that our accuracy and precision calculations are comparable to (or better than) other studies of interlaboratory variability of measurements in blood gases and pH[8-12] and recent assessments of continuous arterial blood gas and pH monitors.[13-16]

Table 4 Assessment of Interchangeability of a New OPTI 1 and an Established Analyzer ABL 500.[a]

| | Acceptable CLIA Performance[b] | OPTI 1-ABL 500 Differences (Observed Means ± 2 SD) |
|---|---|---|
| pH (units) | ± 0.04 | −0.04 to + 0.02 |
| $P_{CO_2}$ (torr) | ± 5 | −1.29 to + 4.47 |
| $P_{O_2}$ (torr) | ± 15.51 | −13.82 to + 6.10 |

[a] A new analyzer is considered interchangeable with an established analyzer if the mean ± 2 standard deviations (SD) of the observed differences on the same sample are within the CLIA mandated targets.

[b] 80% of samples must be within the range of target.

[c] Three SD of midrange $P_{O_2}$ samples from 1,848 laboratories reporting to the College of American Pathology aqueous blood gas survey, 1995.

Provided that accuracy and precision are acceptable, point-of-care analyzers offer important advantages over conventional analyzers in a number of clinical situations. These include potentially low expense, portability, and the capability to be rapidly calibrated and readied to run samples, without extensive warm-up and quality control procedures. The particular analyzer we used incorporates optical fluorescent sensors. These analyzers operate by measuring fluorescence that is produced when $O_2$, $CO_2$, and $H^+$ interact with specific fluorescing chemicals immobilized in the sample chamber. Medicare-CLIA regulations require 2-point calibration and quality control testing every 8 hours, and either a 1-point calibration every 30 minutes or a 1-point calibration prior to testing. Quality control is achieved in the system that we studied by using a 6-point calibration procedure with each manufactured batch of sample chambers. This involves calibration of the chamber by the manufacturer and imprinting this information on a bar code attachment on the chamber. The analyzer 'reads' this bar code to obtain the calibration information. In addition, an aqueous buffer is present in each sample chamber to provide a 1-point calibration signal immediately prior to analysis.

## In Conclusion

We believe our data indicate that the OPTI I analyzer has acceptable accuracy and precision to be used clinically. Other systems using different analysis and calibration techniques also exist (Table 1). Accuracy and precision for any POC system should be established before the device is recommended for widespread use.

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# Accuracy of Electrolyte and Blood Gas Determinations from Samples Collected in Preheparinized Syringes

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**BACKGROUND: We sought to determine whether commercially prepared, heparinized syringes provide accurate results for both blood gas and electrolyte analysis of whole-blood samples. Because of heparin binding, either an electrolyte-balanced syringe or one containing only minimal amounts of heparin must be used to ensure accurate values for electrolytes in whole-blood determinations. METHODS & MATERIALS: We evaluated 3 commercially available heparinized syringes: (1) Becton Dickinson (BD) standard 5-mL liquid-heparin syringe, 100 units lithium-heparin/mL, (2) Radiometer electrolyte-balanced heparin 3-mL syringe (EB-R), containing $Ca^{++}$-, $Na^{+}$-, and $K^{+}$-heparin in lyophilized form, 40 units/mL; and (3) Martell electrolyte-balanced heparin 3-mL syringe (EB-M), containing Li- and Zn-heparin in lyophilized form, 16.7 units/mL. Blood samples from 13 normal volunteers and 8 critically ill ICU patients were drawn into BD, EB-R, and EB-M syringes and into BD SST gel tubes (control). Blood was assayed on a Ciba-Corning Model 288 analyzer, and values for $Ca^{++}$, $Na^{+}$, and $K^{+}$ were compared with values obtained from the corresponding serum specimens from the vacuum tubes. Results were assessed by 1-way analysis of variance (ANOVA), with $p < 0.05$ considered statistically significant. RESULTS: Whole-blood specimens collected in the BD syringe yielded values for $Ca^{++}$ that were statistically significantly lower than serum values from samples containing no anticoagulant (values decreased by 0.1 mmol/L). $Na^{+}$ and $K^{+}$ values obtained from BD syringes were less affected. ($Na^{+}$ values differed by < 3 mEq/L and $K^{+}$ values < 0.2 mEq/L.) Results of analysis of whole-blood samples collected in EB-R and EB-M syringes did not differ significantly from results obtained from analysis of serum specimens (difference for $Ca^{++}$ < 0.02 mmol/L, for $Na^{+}$ < 2 mEq/L, and $K^{+}$ < 0.2 mEq/L). Blood gas determinations were not different among the 3 heparinized syringes. No clotting problems were observed with either the EB-R or EB-M syringes. CONCLUSIONS: We conclude that collection in the BD syringe leads to falsely low $Ca^{++}$ results because of the syringe's high heparin content. The EB-R and EB-M syringes can be used to accurately assess whole-blood $Na^{+}$, $K^{+}$, and $Ca^{++}$.** [Respir Care 1996;41(9):805-808]

The authors are associated with the Veteran Affairs Puget Sound Health Care System, Seattle Division, Seattle, Washington.

The authors have no financial interest in the products described in the study or in competing products.

Mr Hussey presented an abstract based on this study at the OPEN FORUM during the 41st Annual Convention and Exhibition of the American Association for Respiratory Care in Orlando, Florida, December 3-6, 1995.

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## Background

Measurements of ionized calcium ($Ca^{++}$) are used increasingly in circumstances in which values for total calcium provide an incomplete picture of physiologic status, eg, in patients with altered proteins (as in chronic renal failure, nephrotic syndrome, or malabsorption) and in disturbances of acid-base metabolism (as in surgical patients who have received citrated blood, heparin, bicarbonate, or intravenous solutions). Newer instruments in the clinical laboratory now permit whole-blood determinations for arterial blood gas values and also for a variety of electrolytes, including $Na^{+}$, $K^{+}$, and $Ca^{++}$.

A sometimes unrecognized but clinically important problem is the use of heparinized whole-blood specimens for $Ca^{++}$ assays. Heparinized blood is commonly used for arterial blood gas determinations; however, heparin can bind or chelate cations, especially $Ca^{++}$, producing inaccurate value.[1,2] The direction and magnitude of the shift depend upon the cations being observed and the type of heparin used. Commercial products developed to minimize the interference with $Ca^{++}$ include electrolyte-balanced heparin, very-low-concentration heparin, zinc- (Zn) heparin, and a blend of lithium- (Li) and Zn-heparins.

The rationale behind these products is that (1) heparin interference in $Ca^{++}$ assays occurs because heparin binds $Ca^{++}$; (2) heparin has multiple cation-binding sites with varying affinities for cations; (3) addition of Zn binds those sites that have the greatest affinity for divalent cations (eg, $Zn^{++}$ and $Ca^{++}$), and (4) addition of Li binds low-affinity-cation binding sites and minimizes changes in blood gas variables.[3,4]

One study suggests that electrolyte-balanced heparin eliminates the interference with $Ca^{++}$ and other electrolyte determinations in healthy volunteers and patients undergoing surgical procedures.[5] Other studies[1,6] have examined a particular preparation of Li- or Zn-heparin and suggest that they eliminate the interference with $Ca^{++}$ measurements. In $Ca^{++}$, $Na^+$, and $K^+$ analyses of venous blood collected from normal volunteers in syringes with varying amounts of heparin, the bias of $Ca^{++}$ results was found to increase with increased heparin concentration in the syringes.[2]

We were interested in verifying manufacturers' claims for electrolyte-balanced syringes before placing a particular brand into service in our hospital. We had historically used liquid heparin for blood gas analysis, and had acquired new instrumentation that permitted analysis of whole-blood $Na^+$, $K^+$, and $Ca^{++}$. We also wanted to examine the utility of a newer commercial product containing a mixture of Li- and Zn-heparin for determination of $Ca^{++}$, $Na^+$, $K^+$, and blood gas variables in ICU patients. The combined analyses, using blood from both normal volunteers and ICU patients, were performed on newer instrumentation not previously reported.

## Materials & Method

Blood was collected from the forearm veins of 13 normal volunteers and from arterial lines in 8 ICU patients, after informed consent had been obtained from all study subjects in accordance with Department of Veterans Affairs and University of Washington Human Subjects Division policies. We studied 3 commercially available syringes for their effect on electrolyte and blood gas values:* (1) Becton Dickinson (BD) standard 5-mL liquid-heparin syringe, 100 units Li-heparin/mL, (2) Radiometer electrolyte-balanced heparin 3-mL syringe (EB-R), containing $Ca^{++}$, $Na^+$, and $K^+$ heparin in lyophilized form, 40 units/mL; and (3) Martell electrolyte-balanced heparin 3-mL syringe (EB-M), containing Li- and Zn-heparin in lyophilized form, 16.7 units/mL. (The Martell collection device was not evaluated in normal persons because the syringes were not available at the time.) The control was serum collected in a BD Vacutainer SST gel tube containing no anticoagulant. This served as an adequate control because it contained no anticoagulant (to potentially bind cations); additionally, specimens were centrifuged promptly and the serum separated (anaerobically) from cells to prevent artifactual changes in cation concentrations during processing.

Whole-blood heparinized specimens (BD, EB-R, EB-M) and serum control were assessed as appropriate for $Ca^{++}$, $Na^+$, $K^+$, pH, $P_{O_2}$, and $P_{CO_2}$. Electrolyte and pH electrodes of the analyzer were calibrated with 2 buffering solutions, and the $P_{CO_2}$ and $P_{O_2}$ electrodes were calibrated with gas standards provided by the manufacturer. A 2-point calibration was performed automatically every 2 hours, and a 1-point calibration was performed automatically every 0.5 hours. Quality control was assessed using 2 levels of $P_{CO_2}$ and $P_{O_2}$ every 8 hours. Tolerance limits were set at ± 2 standard deviations from a minimum of 20 determinations. Within-run precision, or coefficient of variation (CV) for $Ca^{++}$ was set at < 2%.

Results were assessed by 1-way ANOVA, with $p < 0.05$ indicating statistical significance. The results from the serum control served as a reference or 'true' value.

## Results

Table 1 shows that whole blood $Ca^{++}$ values measured in normal subjects using the BD standard liquid-heparin syringe are significantly lower (decrease of 0.1 mmol/L) compared to control (serum) values. Smaller changes were noted for $Na^+$ and $K^+$. (Values were lower than control serum by < 3 mEq/L for $Na^+$ and < 0.2 mEq/L for $K^+$.). Every specimen collected in the BD syringe exhibited a decreased value for $Ca^{++}$. No statistically significant difference in $Ca^{++}$, $Na^+$, or $K^+$ when compared to serum control was measured for corresponding samples collected in the EB-R syringe.

Table 2 shows that whole-blood $Ca^{++}$ values measured in the BD standard syringe were also lower in ICU patients, compared to EB-R, EB-M, and control. Again, every specimen collected in the BD syringe exhibited a decrease in $Ca^{++}$ compared to control or EB-R or EB-M, but this decrease was not found to be statistically significant. Specimens for $Ca^{++}$ collected in the EB-R and EB-M syringes showed good correlation with serum control, with no statistically significant differences noted. No statistically significant difference in $Na^+$ and $K^+$ measurements were noted in these patient samples when results from samples collected in test syringes were compared to the results of analysis of the serum control.

*Suppliers of commercial products are listed in the Product Sources section at the end of the text.

Table 1. Values* for Electrolytes Obtained from Whole Blood Collected in Various Heparinized Syringes, Compared to Values Obtained from Serum in 13 Normal Subjects.

| Collection Vessel & Specimen | Cation | | | | | |
|---|---|---|---|---|---|---|
| | $Ca^{++}$ mmol/L* | | $Na^{+}$ mEq/L | | $K^{+}$ mEq/L | |
| BD, whole-blood with heparin | 1.155 (0.052) | p = 0.00001 | 138.6 (2.6) | p = 0.006 | 4.01 (0.35) | p = 0.24 |
| EB-R, whole-blood with heparin | 1.270 (0.049) | p = 0.468 | 142.1 (1.6) | p = 0.06 | 3.99 (0.34) | p = 0.19 |
| Vacuum tube, serum with no heparin | 1.257 (0.041) | — | 141.0 (1.2) | — | 4.18 (0.37) | — |

*All electrolyte values are mean (SD). See text for syringe description.
All p values are for comparisons to serum values.

Table 2. Comparison of Electrolyte Values Obtained from Whole-Blood Collected in Heparinized Syringes to Values Obtained from Serum in 8 ICU Patients.

| Collection Vessel & Specimen | Cation | | | | | |
|---|---|---|---|---|---|---|
| | $Ca^{++}$ mmol/L* | | $Na^{+}$ mEq/L | | $K^{+}$ mEq/L | |
| BD, whole blood with heparin | 1.04 (0.07) | p = 0.104 | 133 (1.8) | p = 0.273 | 4.6 (0.6) | p = 0.63 |
| EB-R, whole blood with heparin | 1.14 (0.08) | p = 0.62 | 136 (2.1) | p = 0.06 | 4.6 (0.6) | p = 0.69 |
| EB-M, whole blood with heparin | 1.10 (0.09) | p = 0.771 | 136 (2.5) | p = 0.19 | 4.6 (0.7) | p = 0.78 |
| Vacuum tube (serum, no heparin) | 1.12 (0.10) | — | 134 (1.8) | — | 4.7 (0.7) | — |

*All electrolyte values are mean (SD). See text for syringe description
All p values are for comparisons to serum values.

No statistically significant differences were found in the assay of pH, $P_{CO_2}$, and $P_{O_2}$ among the 3 collection devices in the ICU patient specimens (Table 3). The EB-M syringe exhibited a slightly higher mean $P_{O_2}$ compared to the other two devices. pH values were similar among the 4 collection devices.

Table 3. Values* for Blood Gas Variables Obtained from Whole-Blood Arterial Samples Collected from 8 ICU Patients in Heparinized Syringes Compared to Values Obtained from Serum.

| Collection Vessel & Specimen | pH | $P_{CO_2}$ (torr) | $P_{O_2}$ (torr) |
|---|---|---|---|
| EB-R, whole blood with heparin | 7.37 (0.06) | 38 (4.0) | 149 (99.2) |
| EB-M, whole blood with heparin | 7.37 (0.06) | 38 (4.5) | 154 (104) |
| BD, whole blood with heparin | 7.38 (0.05) | 37 (4.3) | 147 (88.4) |
| Vacuum tube, serum, no heparin | 7.40 (0.05) | — | — |

*Values are mean (SD). See text for syringe description. Values are not statistically significantly different from values for serum pH or for control (BD syringe) for additional blood gas variables

## Discussion

With the advent of newer instrumentation in the clinical laboratory that can measure blood gas variables (ie, pH, $P_{O_2}$, $P_{CO_2}$) and a variety of electrolytes (eg, $Na^{+}$, $K^{+}$, $Ca^{++}$) in whole blood, it is important to assess the effect of sample collection and anticoagulant used on the tests to be determined. To minimize sample collection, it is ideal if one type of anticoagulant can be used to assess all variables of interest.

Liquid Li-heparin is a common anticoagulant used for blood gas determinations. However, the BD standard syringe containing liquid Li-heparin underestimates $Ca^{++}$ values in normal persons, compared to EB-R and control. It also underestimates $Ca^{++}$ values in ICU patients compared to EB-R, EB-M, and serum control. Many hospitals heparinize syringes for collection of $Ca^{++}$ by drawing up a concentrated solution of liquid Li-heparin and expelling the excess before sampling blood. This practice may still introduce inaccuracies because of binding of $Ca^{++}$ by residual Li-heparin and the dilution of the specimen, by the heparin solution in the dead space of the syringe.

By contrast, whole-blood $Ca^{++}$, $Na^{+}$, and $K^{+}$ measured in the EB-R or EB-M (electrolyte-balanced Radiometer or Martell syringes) were not significantly different from control (serum) values. This indicates that these syringes with lyophilized heparin are superior to liquid heparin for $Ca^{++}$ determinations because the possibility of specimen dilution is eliminated, the amount of heparin present in the syringe is balanced (to prevent excess cation chelation), and the concentration of heparin is tightly controlled. The 3 syringes did not have clinically significant differences in $Na^{+}$ or $K^{+}$ results compared to serum control, and no statistically significant differences in blood gas variables were noted. However, this decrease was not as marked (as compared with data in Table 1), possibly because these ICU patients were already hypocalcemic. (Note the low mean $Ca^{++}$ of the control specimen.) Thus, the decrease in $Ca^{++}$ observed in the sample from the BD syringe was not

found to be statistically significant in this patient population. The small negative bias (−2.4 mEq/L) in mean sodium values among normal volunteers observed when the BD syringe was compared to serum is less than the "medically allowable error" cited in the literature for this analyte.[6] Similar findings were reported for the EB-R and a slightly different lyophilized Li-heparin product (with no Zn, and less heparin) made earlier by Martell.[5]

Throughout the study, no clotting problems were observed with either of the electrolyte-balanced syringes, despite their lowered heparin content. However, good mixing of the lyophilized heparin with the specimen is essential. If an electrolyte-balanced syringe is not used, studies suggest that a product containing sodium- or lithium-heparin at concentrations < 10 IU/mL may be used.[3,4] We presume that a heparin concentration this low avoids any significant chelation (binding) effect on cations. However, with lower heparin concentrations, there is increased potential for specimens to clot either before or during analysis.

The problem of anticoagulant and chelation of cations in the measurement of whole-blood analytes must be kept in mind as new instrumentation (with even broader test menus) becomes available. Ionized magnesium determinations are now available on some analyzers, and the utility of the balanced heparin or Li- and Zn-heparin combinations must be assessed in the determination of this constituent. Also, measurement of total Ca or Mg may be affected by use of these anticoagulants. Studies have indicated that the balanced heparin overestimates total Ca because Ca has been added to help titrate the binding sites on heparin.[1] However, the lyophilized Li- and Zn-heparin appears to be suitable for measurement of total Ca.[1] Total Mg measurements exhibit a modest bias (0.08 mmol/L) when assayed in the presence of the Li- and Zn-heparin.[7]

Many commercial products are available for collection of whole-blood specimens. The types of analytes to be determined must be considered when a device is selected. It seems clear from our study and others that liquid heparin should be avoided for $Ca^{++}$ determinations, and that a lyophilized product, such as the EB-M or EB-R offers advantages, when whole-blood $Ca^{++}$ (in addition to $Na^+$, $K^+$, and blood gases) is to be measured.

## PRODUCT SOURCES

**Heparinized Syringes:**

5-mL liquid heparinized syringe, 100 units lithium-heparin/mL, Becton-Dickinson, Franklin Lakes NJ

3-mL electrolyte-balanced heparin in lyophilized form, 40 units/mL, Radiometer America, Westlake OH

3-mL electrolyte-balanced heparin syringe (EB-M), Li- and Zn-heparin in lyophilized form, 17 units/mL, Martell Medical Products, Temecula CA

**Collection Vessel (for serum, without heparin):**

BD Vacutainer SST gel tube, Becton-Dickinson, Franklin Lakes NJ

**Blood Gas Analyzer:**

Ciba Corning 288 and Ciba Corning 850, Ciba Corning Diagnostics, Medfield MA

Radiometer 620, Radiometer America Inc, Westlake OH

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# Comparison of Three Humidification Techniques during Mechanical Ventilation: Patient Selection, Cost, and Infection Considerations

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**BACKGROUND: This study sought to confirm eligibility criteria, compare costs, and evaluate the effects of humidification technique on circuit colonization and nosocomial pneumonia in mechanically ventilated patients. MATERIALS & METHODS: After evaluation, patients eligible for use of a passive humidifier (n = 200) were randomized to receive either a hygroscopic condenser humidifier (HCH) or heated humidifier and heated-wire circuit (HWC), Group A. Patients ineligible for Group A (Group B) were randomized to receive heated humidification with HWC or without a heated-wire circuit (NHWC). Maximum and minimum body temperature, number of suctioning procedures, secretion volume, secretion quality, volume of instilled saline, number of times circuit was drained, and the number of circuit disconnections were recorded daily, and costs of devices and maintenance were calculated. Sputum, ventilator circuits, and humidification devices of patients requiring > 24 hours of ventilatory support were swabbed and cultured. Incidence of tracheal tube occlusion and of nosocomial pneumonia were also recorded. RESULTS: Of the patients, 51.5% were eligible for HCH. Surgical patients were more likely to meet criteria for HCH use than were medical patients (67% vs 19%, $p < 0.001$). Ineligibility for HCH use was based on the presence of thick (63%) or bloody secretions (22%), hypothermia (8%), or a combination of these conditions (7%). Patients in Group B were sicker, required ventilatory support longer, and had thicker and greater volumes of secretions. Nosocomial pneumonia was more likely in Group-B patients but was similar between humidification devices within each group. Circuit disconnections were greatest in the NHWC group. Costs were significantly less for HCH on Day 1 ($5.23 vs HWC = $30.22 vs NHMC = $27.79, $p < 0.001$). On Day 5, costs/day still favored HCH ($4.70 vs $8.97 vs $17.96, $p < 0.01$). No incidence of tube occlusion was seen. CONCLUSIONS: HCH use in surgical patients can be safe and effective (67%). Medical patients are less likely to be eligible for HCH use (19%). For 1 day's use, HCH is significantly less costly than the other techniques. After 5 days, costs of HCH and HWC diminish, whereas costs of NHWC remain high. An algorithm that directs choice based on patient need helps assure safe, effective humidification. Humidification devices do not influence the incidence of nosocomial pneumonia.** [Respir Care 1996;41(9):809-816]

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## Introduction

Humidification of inspired gases during mechanical ventilation is a standard of care.[1,2] A number of investigations in the past 20 years have demonstrated the adverse effects of inadequate humidity on tracheobronchial structure and function.[3-6] These effects include inspissation of secretions, ciliary dyskinesis, and epithelial desquamation.[3-6] The most common technique for providing humidity during ventilatory support is heated humidification. In recent years, passive humid-

ifiers, or artificial noses, have been successfully used on selected patients.[7-9] We have previously reported our experience using passive humidifiers applied by algorithm to surgical patients.[7] The current study was designed to answer questions raised by our previous work. The aims of the study were (1) to determine the eligibility for passive humidifier use in medical and surgical patients; (2) to evaluate contamination issues with a new once-a-week circuit-change frequency; and (3) to analyze differences in costs among the humidification devices at the new circuit-change frequency.

## Materials & Methods

The study was approved by the institutional review board (IRB) governing human research, and the need for informed consent was waived. All patients requiring mechanical ventilation in the surgical intensive care unit (SICU) and medical intensive care unit (MICU) at the University of Cincinnati were eligible for participation. Patients in the recovery room and postoperative cardiac surgery patients were not eligible due to the typically limited period of ventilatory support (< 24 h).

Three methods of humidification were studied: (1) passive humidification using a hygroscopic condenser humidifier (HCH); (2) heated humidification with a dual heated-wire circuit set to deliver gas at a temperature of 36° C at the Y-piece and at 35° C in the humidification chamber (HWC); and (3) heated humidification set to deliver gas at 34° C at the Y-piece with a circuit that did not contain heating wires (NHWC). Heated humidification was provided by a MR-730 humidifier (Fisher & Paykel, Auckland, New Zealand) with or without a dual heated-wire circuit. Chambers were the same for both systems and an intermittent water feeding system was utilized. The temperature ranges were chosen for several reasons. The 34° C setting during heated humidification is the current standard in our unit and is supported by the literature as mimicking normal upper airway function.[10] The 36° C setting with a heated-wire circuit allows a chamber temperature of 35° C and elimination of condensate in the circuit. This temperature was selected after determining the practice of local institutions using heated-wire circuits. Extension (flex) tubes between the Y-piece and the artificial airway were used only in patients with tracheostomies. The passive humidifier was a Baxter nonfiltered HCH (Baxter Healthcare Corp, Round Lake IL). This device has a clear plastic housing and uses a lithium-chloride-treated foam insert. The manufacturer reports that this device has a dead space of 35 mL, resistance of 1.8 cm $H_2O \cdot s \cdot L^{-1}$, and a moisture output of 29.5 mg $H_2O$/L at a tidal volume ($V_T$) of 1,000 mL and frequency of 10 breaths/min.[11]

Patients were screened according to a previously published algorithm (Fig. 1) to determine which patients had contraindications to HCH use.[7] Our previous work suggests the use of an algorithm prevents endotracheal tube (ETT) occlusion seen by other authors using HCHs. After this initial screening, patients were randomized according to Fig. 2. This protocol was chosen to safely allow comparison of device performance and costs in like populations. This technique created 4 groups of patients to be studied. Group A consisted of patients eligible for HCH use, and Group B of patients ineligible for HCH use.

- HCH—Group A1. Patients eligible for HCH use who were randomized to use an HCH
- HWC—Group A2. Patients eligible for HCH use who were randomized to use heated humidification and a heated-wire circuit
- HWC—Group B1. Patients ineligible for use of an HCH according to the algorithm who were randomized to use heated humidification and a heated-wire circuit
- NHWC—Group B2. Patients ineligible for use of an HCH according to the algorithm who were randomized to use a heated humidifier with a circuit that did not contain heating wires.

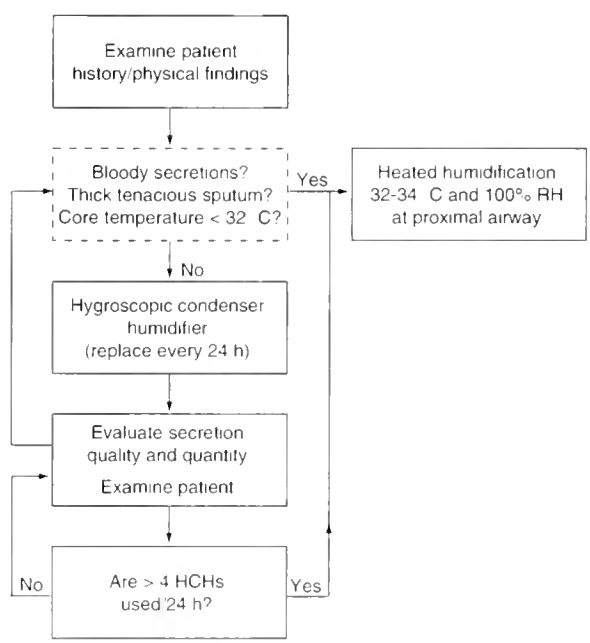


Fig. 1. Algorithm used to determine whether patients were eligible for use of a hygroscopic condenser humidifier (HCH). RH = relative humidity.

Randomization was accomplished using the last digit in the patient's medical record number. In Group A, patients with an odd medical record number received an HCH and those with an even number received a heated humidifier with a heated-wire circuit. In Group B, patients with an odd medical record number received heated humidification without a heated-wire circuit, and those with an even number received

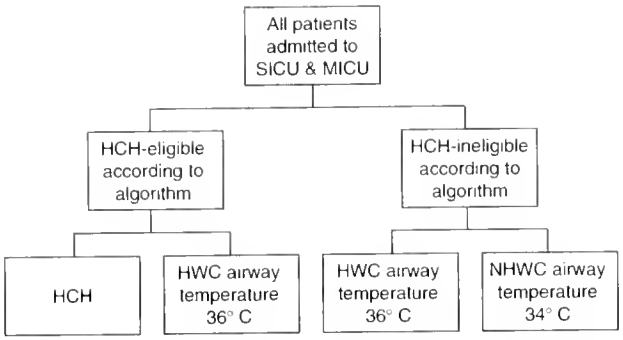


Fig. 2. Scheme for randomization of patients into groups based on the algorithm shown in Figure 1. HCH = hygroscopic condenser humidifier; HWC = heated-wire circuit; NHWC = circuit without heating wires.

heated humidification with a heated-wire circuit. Randomization was accomplished at the bedside by the respiratory care practitioners.

During the course of ventilatory support, daily maximum and minimum body temperatures were transcribed from bedside records. Suctioning was performed on an as-needed basis by respiratory care and nursing staff. Suctioning was indicated when secretions were present in the tracheal tube, audible evidence of secretions were present, or auscultation revealed rhonchi. Suctioning was performed using open-circuit, single-use catheters, and sterile technique. The number of suctioning attempts/day, the volume and quality of secretions, and the volume of instilled normal saline were recorded. Secretion volume was measured by collecting secretions in a graduated trap in line with the suction tubing. Instilled saline was measured by counting the number of unit dose (5 mL) vials used. Secretion quality was based on the scheme of Suzukawa et al.[12] Secretions were defined and coded as thin (1), moderate (2), or thick (3) according to the following definitions.

- Thin—Following the suctioning procedure, the catheter appears clean.
- Moderate—Following the suctioning procedure, secretions adhere to the side of the catheter but are easily removed by aspirating saline through the catheter.
- Thick—Following the suctioning procedure, secretions adhere to the catheter and are not removed by aspirating saline through the catheter.

We also recorded the number of circuit disconnections/day. A circuit disconnection was defined as any interruption of the circuit and included suctioning attempts, emptying condensate, changing the circuit or circuit components, removing the HCH for bronchodilator treatments, and any other circumstance that resulted in violation of the circuit. Heated humidifiers were filled through a closed-feed system and such filling was not considered a circuit disconnection. The number of devices used for humidification was also recorded daily and includes water, circuits, water traps, HCHs, and humidification chambers.

Patients requiring longer than 24 hours of mechanical ventilatory support had sputum cultures and cultures of the ventilator circuit Y-piece and, depending upon the device used, of the patient side of the HCH or the water bath. Cultures were performed after 24 hours and then every 48 hours thereafter, as long as the patient remained on the ventilator. Cultures were obtained by swabbing a 1-$cm^2$ area of the desired equipment. Bacteriologic samples were immediately transferred to the laboratory for Gram stain and culture in conventional solid and liquid media. Culture results were qualitative. The incidence of nosocomial pneumonia was determined by standard criteria that included all of the following: purulent sputum, respiratory cultures containing potentially pathogenic organisms, fever (> 38.0° C), and new infiltrates on chest radiograph. Pathogenic organisms included Gram-positive, Gram-negative, and fungal organisms which are not part of the normal flora of the respiratory tract.

Cost of humidification devices was calculated from the individual price of disposable equipment and the time that the therapist spent maintaining the equipment. Circuits were changed every 7 days, and HCHs were replaced daily (more frequently if partially occluded by sputum). Costs were identified from purchasing records based on signed bids from the manufacturer and are shown in Table 1. Costs for heated humidification were based on an initial kit charge, which for HWC and NHWC included a chamber, 2-L bag of water, and feed set. Individual costs per device were used as these components were added to the system. The kit included most of the equipment necessary to set up a ventilator and was purchased from the manufacturer at a cost less than the sum of the individual components. Therapist time was calculated based on the mean salary of all respiratory care practitioners (RCPs) working in the intensive care units and any time spent providing maintenance of the humidification system (adding water, changing components, emptying condensate). Each contact with the patient for emptying condensate was assigned a time value of 5 minutes. This is based on our observation that emptying condensate requires hand washing before and after, and proper removal and disposal of the condensate. This requires an average of 5 minutes. Changing the ventilator circuit required 10-15 minutes. Each intervention by RCPs was noted on a log sheet attached to the ventilator. Log sheets were collected and tallied daily. Costs were calculated on a daily basis. Any additional equipment used was added to the cost and divided by the days of use. Costs then were a function of disposable equipment used and length of use.

Patients who developed thick or bloody secretions during HCH use were switched to heated humidification with a heated-wire circuit. The incidence of ETT obstruction was also recorded. Tracheal tube obstruction was defined as the inability to pass a 10-French suction catheter down the ETT.

Table 1 Total Costs Associated with the 3 Humidification Devices Studied

| Associated Equipment | Device | | |
|---|---|---|---|
| | HCH* | HWC | NHWC |
| Setup Kit | NA | $24.95 | $12.97 |
| Circuit | $1.18 | 14.95 | 1.18 |
| Water (2 L) | NA | 3.51 | 3.51 |
| Water Trap | NA | NA | 1.34 |
| HCH | 2.05 | NA | NA |
| Chamber | NA | 8.10 | 8.10 |
| Therapist Time/h | 12.00 | 12.00 | 12.00 |
| Total equipment cost for 24 h | $3.23 | $24.95 | $12.97 |

*HCH = hygroscopic condenser humidifier, HWC = heated wire circuit, NHWC = circuit without heating wires, NA = not applicable

Table 2. Results of Randomization of Patients According to the Scheme Shown in Figure 2.

| | Total | SICU* | MICU |
|---|---|---|---|
| Number of patients | 200 | 136 (68) | 64 (32) |
| HCH-Eligible | 103 (51.5) | 91 (67) | 12 (19) |
| HCH–Group A1 | 49 (24.5) | 43 (32) | 6 (9) |
| HWC–Group A2 | 54 (27) | 48 (35) | 6 (9) |
| HWC–Group B1 | 49 (24.5) | 24 (18) | 25 (39) |
| NHWC–Group B2 | 48 (24) | 21 (15) | 27 (42) |

*SICU = surgical intensive care unit; MICU = medical intensive care unit, see text for eligibility criteria for groups. HCH = hygroscopic condenser humidifier; HWC = heated-wire circuit, NHWC = circuit without heating wires.
† $p < 0.001$ SICU vs MICU

Patient demographics were also collected and included age, diagnosis, history of chronic lung disease, and Simplified Acute Physiology Score (SAPS).[13] Statistical analysis was performed using analysis of variance and $\chi^2$ to determine differences between groups. A p value $< 0.05$ was considered statistically significant.

## Results

During a 9-month period, 214 patients were eligible for the study. Of the eligible patients, 14 expired within 6 hours of admission or were transferred and lost to follow-up. The remaining 200 patients had all the necessary data collected for analysis.

Of the 200 patients, 136 (68%) were in the SICU and 64 (32%) were in the MICU. The results of application of the randomization scheme are shown in Table 2. Slightly over one half (51.5%) of all patients were eligible for HCH use, according to the algorithm. However, difference in the number of patients eligible for HCH use between SICU and MICU patients was statistically significant (67% vs 19%, $p < 0.01$). Reasons for ineligibility for HCH use were thick secretions 63% (61/97), bloody secretions 22% (21/97), hypothermia 8% (8/97), and a combination of two or more of these conditions 7% (7/97). In the MICU, 1 patient was switched from an HCH to an HWC after 5 days of use, 16% (1/6). In the SICU, 3 patients were switched from an HCH to an HWC, 2 for thick secretions and 1 after 5 days of use, 7% (3/43).

There was no difference in age, daily minimum and maximum temperatures, or incidence of ETT obstruction among the 4 groups. Table 3 shows the measured variables in the study. Patients in Group B, HWC and NHWC, required more frequent suctioning procedures, had longer duration of ventilatory support, thicker secretions, and larger secretion volume than patients in Group A, HCH and HWC. Patients in Group B also had a significantly higher SAPS score, mean (SD), [HCH = 9 (3), HWC = 8 (4), vs HWC = 19 (5), NHWC = 17 (5)] than patients in Group A. Comparison of data between HCH and HWC in Group A, failed to reveal any differences in suctioning variables, circuit disconnections, or secretion quality. Comparison of data between HWC and NHWC in Group B, showed no difference in secretion volume, secretion quality, ETT obstruction, volume of saline instilled, suctioning attempts, minimum and maximum temperatures, or ventilator days. There were differences between these groups related to the number of times condensate was required to be removed from the circuit [1.1 (1.4) vs 9.4 (1.8), $p < 0.001$] and number of circuit disconnections [10.3 (4.3) vs 20.0 (4.2), $p < 0.001$].

The incidence of nosocomial pneumonia was significantly less in Group A compared to Group B (6% and 6% vs 16% and 10%). There was no difference between HCH and HWC in Group A or between HWC and NHWC in Group B with respect to the incidence of pneumonia. The difference between HWC and NHWC in Group B was 6% (16% vs 10%, $p = 0.093$), a value not statistically significant. Positive sputum cultures were seen in one third to one half of all patients. Group B HWC had a significantly higher rate of positive sputum cultures compared to the other 3 groups (49% vs 38%, 33%, and 33%, $p < 0.01$). All patients in the HCH group with positive sputum cultures had positive HCH cultures. In the HWC groups, the incidence of positive humidification-chamber cultures was 0% (Group A) and 10% (Group B). No patient in the NHWC group had a positive humidifier-chamber culture. Positive circuit cultures were seen in 10% of all patients in the HCH group, 17% of patients in Group A HWC, 41% of patients in the Group B HWC, and 31% of the NHWC group. These differences were significant for Group A compared to Group B ($p < 0.05$). Comparison of circuit colonization between the HCH and HWC (Group A) failed to show a significant difference (10% vs 17%, $p < 0.59$). Comparison of Group B HWC and NHWC failed to demonstrate a significant difference in circuit colonization (HWC = 41% vs NHWC = 31%, $p = 0.063$). In every circumstance, organisms cultured from the ventilator circuits, humidifier chambers, and HCHs were the same organisms isolated from the patient's sputum.

Table 3. Comparison of Demographic, Suctioning, System Maintenance, and Bacteriologic Data among the 4 Groups Studied

| Variable | Group A* | | Group B | |
|---|---|---|---|---|
| | HCH Group A1 | HWC Group A2 | HWC Group B1 | NHWC Group B2 |
| Age (years) | 44 (14) | 41 (15) | 52 (19) | 45 (17) |
| Ventilator days | 4.5 (3.9) | 4.1 (3.2) | 10.8 (6.5) | 8.9 (9.2) |
| Patients with tracheostomy | 2 (5%) | 3 (7%) | 7 (14%) | 3 (7%) |
| Maximum 24-h temperature | 37.5 (0.7) | 37.3 (0.8) | 38.1 (1.1) | 37.8 (0.9) |
| Minimum 24-h temperature | 36.5 (0.7) | 36.7 (1.0) | 36.2 (1.1) | 36.6 (0.9) |
| Suctioning events/day | 6.5 (2.5) | 5.2 (2.3) | 9.8 (3.9) | 8.3 (3.7) |
| Secretion volume, mL/day | 20.4 (16.6) | 23.0 (14.0) | 32 (17.4) | 34.2 (20.8) |
| Circuit drains/day | 0 | 1.1 (1.3) | 1.1 (1.4) | 9.4 (1.8)§ |
| Circuit disconnections/day | 8.6 (2.7) | 8.5 (2.4) | 10.3 (4.3) | 20.0 (4.2) |
| Saline volume mL/day | 10.9 (8.0) | 7.1 (5.2) | 11.2 (6.9) | 13.6 (8.8) |
| ETT obstruction | 0 | 0 | 0 | 0 |
| Secretion quality 1.5(0.5) | 1.5 (0.6) | 1.5 (0.6) | 2.2 (1.1) | 1.9 (0.8) |
| Pneumonia | 3 (6%) | 3 (6%) | 8 (16%)‖ | 5 (10%) |
| Positive sputum culture | 19 (38%) | 17 (33%) | 24 (49%)‖ | 16 (33%) |
| Positive circuit culture | 5 (10%) | 9 (17%) | 20 (41%) | 15 (31%) |
| Positive chamber culture | NA | 0 (0%) | 5 (10%) | 0 (0%) |
| Positive HCH culture | 19 (38%) | NA | NA | NA |
| SAPS | 9 (3) | 8 (4) | 19 (5) | 17 (5)¶ |

*See text for eligibility criteria for groups. Values are mean (SD) unless otherwise indicated. HCH = hygroscopic condenser humidifier, HWC = heated-wire circuit, NHWC = circuit without heating wires, ETT = endotracheal tube; SAPS = Simplified Acute Physiology Score.
†$p < 0.01$ vs Groups A1 and A2.
‡$p < 0.05$ compared to Groups A1 and A2
§$p < 0.01$ vs Groups A1, A2, B1.
‖$p < 0.01$ vs Group B1
¶$p < 0.01$ vs Groups A1, A2, B2

Daily costs for each type of humidification and the cost difference between devices are shown in Table 4. For 24 hours of ventilatory support, use of an HCH was significantly cheaper than HWC or NHWC. As duration of ventilatory support increased, the cost differences among HCH and HWC and NHWC became smaller, whereas the differences among HCH and NHWC became larger. On Day 5, the cost of HCH use/day was $4.70, compared to $8.97 for HWC and $17.96 for NHWC.

Table 4. Total Cost/Day for Each of the 3 Humidification Techniques (Assuming Circuit Change Interval of 7 Days).

| Device | Day 1 | Day 2 | Day 3 | Day 4 | Day 5 |
|---|---|---|---|---|---|
| | Costs | | | | |
| HCH | $5.23 | $4.64 | $4.51 | $4.40 | $4.70 |
| HWC | 30.22 | 16.11 | 12.58 | 9.93 | 8.97 |
| NHWC | 27.79 | 21.65 | 19.60 | 18.58 | 17.96 |
| | Cost Differences | | | | |
| HCH vs HWC | 24.99 | 11.47 | 8.07 | 5.53 | 4.27 |
| HCH vs NHWC | 22.56 | 17.01 | 15.09 | 14.18 | 13.26 |
| HWC vs NHWC | 2.43 | 5.54 | 7.02 | 8.65 | 8.99 |

HCH = hygroscopic condenser humidifier; HWC = heated-wire circuit, NHWC = circuit without heating wires

## Discussion

The results of this study confirm our previous work related to the successful use of an algorithm to safely apply the appropriate humidification device to mechanically ventilated patients. The results also support findings that suggest that the humidification device does not influence the incidence of nosocomial pneumonia.[7-9] This study was undertaken to further define the use of HCH in patients with a primary medical diagnosis and evaluate the efficacy of heated humidification with a heated-wire circuit.

In our previous study of SICU patients, we found that 73% of patients were eligible for HCH use.[7] In the current study, 67% of SICU patients were eligible for HCH use, but only 19% of MICU patients met the criteria for HCH use. We anticipated finding a decrease in the use of HCH in the MICU but not of the magnitude discovered in the study. The majority of patients in the MICU have pre-existing lung disease and are admitted to the MICU with a known secretion-removal problem. Because using an HCH, regardless of efficiency, always results in water loss from the respiratory tree, we believe that patients with thick secretions should be placed on heated humidification. The use of heated humidification can either add, neutralize, or allow loss of water from the respiratory tree, depending upon humidifier settings. We believe that the temperature we chose mimicked the temperature and humid-

ity of gases entering the trachea during nose breathing. We also found that bronchodilator administration is more frequent in the MICU than the SICU. When an updraft nebulizer is used, the HCH must be removed from the circuit during the treatment period. Use of a metered dose inhaler (MDI) and MDI adapter can eliminate this problem if the adapter fits between the HCH and ETT. However, if a spacer or reservoir is added to the MDI adapter in the inspiratory limb of the ventilator circuit, the HCH should be removed from the circuit. These factors lead us to conclude that patients with chronic lung disease and secretion removal problems are poor candidates for HCH use.

Dreyfuss et al[8,9] have studied humidification in MICU patients and used HCH in all patients successfully. This approach is contrary to our experience and position. According to the first study by Dreyfuss and colleagues,[8] tracheal tube obstruction occurred in 1 patient using an HCH and "emergency change of the filter" was required in 6 instances (6/61, 10%). None of these filter changes was associated with a complication. In their second study,[9] in which each HCH was used for 48 hours, 8 instances of emergency filter change were required (8/68, 12%). In our study, 1.1 HCH were used each 24 hours. This means some patients required changing of an HCH due to contamination with secretions. We did not document any emergency changes or ETT occlusions. We believe that more patients could use an HCH than are identified by our algorithm—but not without risk. The cost savings of using an HCH are highlighted by Dreyfuss and colleagues, but we believe a serious complication in a single patient due to HCH use (ie, ETT obstruction) would eliminate any cost savings obtained using HCH in the previous 100 patients. Our algorithm may appear to be overly conservative, but we believe that liberalizing HCH use may increase risk unnecessarily.

In a series of 4 studies using the Pall HME, ETT obstruction was a common finding.[14-17] Martin et al reported an incidence of 19% (6/32);[14] Cohen et al reported an incidence of 9% (17/170);[15] Misset et al reported an incidence of 13% (4/30);[16] and Roustan et al an incidence of 16% (9/55).[17] These reports led us to develop the algorithm because none of the reports excluded patients with known secretion problems. Each of these studies also used the Pall HME, which has a moisture output of only 21 mg $H_2O$/L (with $V_T$ = 1.0 L), whereas Dreyfuss et al[8,9] used the DAR Hygrobac, which has a moisture output of 31 mg $H_2O$/L (with $V_T$ = 1.0 L). This 30% increase in moisture output may be responsible for the different outcomes in these reports.

Comparison of the 3 humidification devices in this study requires consideration of the patient population. Patients ineligible for HCH use were sicker, mechanically ventilated for longer periods, frequently had pre-existing lung disease, and had thicker secretions. The group of patients deemed eligible for HCH use by the algorithm averaged only 4 days of mechanical ventilation and primarily were surgical patients with no history of lung disease. This is part of the design of the study and unrelated to the humidification device used. We believe these differences necessitate changing humidification strategies to meet patient needs.

Heated humidification with a NHWC was associated with a significantly greater number of circuit disconnections (to empty condensate), used more water, and required more therapist time to maintain compared to HWC and HCH. Use of the NHWC resulted in an average of 9 circuit disconnections each day simply to empty condensate. When you consider that this procedure requires practitioners to wash their hands, empty the condensate, and wash hands again, this procedure typically consumes 5 minutes. With NHWC use, 45 minutes of practitioner time is spent removing condensate from the circuit/day. The costs of maintaining an NHWC in our study caused them to exceed HWC costs. In different institutions and in different countries, these costs may be different. Each institution should evaluate the labor costs of using humidification systems. When an HCH is used, there is no condensate to empty from the circuit—one of the advantages of HCH use. We chose to allow only a 1° C offset between the humidification chamber and airway temperature when a heated humidifier with a HWC was used. This allowed some condensate to accumulate in the circuit, which required emptying 1.1 times/day. Condensate can be completely eliminated from the HWC by allowing temperature to increase as gas travels up the circuit to the patient. However, this practice can result in gas at a relatively high temperature (37° C) to be delivered at a low relative humidity. For instance, if chamber temperature is 33° C (maximum absolute humidity of 36 mg $H_2O$/L) and airway temperature is 37° C (maximum absolute humidity of 44 mg $H_2O$/L), the relative humidity delivered to the patient is 81%. Several authors have suggested that the delivery of warm gas at low relative humidity (which can occur with HWC) may cause drying of secretions and plugging of artificial airways.[18-20] Our results demonstrate that using a temperature offset of 1° C and visible confirmation of a small amount of condensate in the circuit eliminates this concern.

The association between nosocomial pneumonia and respiratory care equipment, including humidifiers, ventilator circuits, and nebulizers, is a nebulous one.[21,22] Early work by Craven et al[23] found that contaminated condensate aerosolized via an in-line nebulizer may cause nosocomial pneumonia. Craven and co-workers[24] suggested that nebulizers be taken out of the circuit when not in use and that ventilator circuits be changed every 48 hours. Recent work by Dreyfuss et al,[25] Hess et al,[26] and others[27] have found that increasing ventilator-circuit-change intervals to 1 week or longer is as safe or safer than 48-hour changes. Two of these reports suggest that never changing the ventilator circuit, except between patients, is the safest, most cost-effective strategy.[25,27]

Because using HWC and HCH can reduce the accumulation of condensate, it has been suggested that these devices can reduce the incidence of nosocomial pneumonia. However, the results of this study as well as of our previous work[7] and

the work by Dreyfuss et al[8,9] suggest that the type of humidification device employed fails to have an impact on the incidence of nosocomial pneumonia. In our previous study, circuit colonization in a group of patients using an HCH was not found. In this study, positive circuit cultures were found in 10% of patients in the HCH group. This compares to 17% in the HWC group, 41% in the HWC (HCH-ineligible) group, and 31% in the NHWC group. All organisms isolated in the circuit were also identified in the sputum. In every case, when an HCH was used, if sputum cultures were positive, cultures of the HCH media were positive for the same organism.

We also noted that 10% of patients in the HWC (HCH-ineligible) group had positive humidification-chamber cultures. In each instance, the organism had previously been isolated in the sputum. In the HWC (HCH-eligible) group, none of the chamber cultures were positive. This suggests that time is required for the chamber to be colonized because patients in the group averaging 4 days of ventilatory support failed to yield positive chamber cultures. No chamber in the NHWC group grew bacteria. This is probably due to the high-operating temperature of the humidifier when a NHWC is used. In order to achieve 34° C at the airway, chamber temperature is typically > 44° C. At this high temperature, many organisms are killed. When a HWC is used, gas at the airway is often warmer than the chamber temperature, which remains near body temperature. This lower chamber temperature appears to allow bacteria to survive in certain instances. The importance of this finding is uncertain. Because these devices function like pass-over humidifiers, only molecular water is produced. If this is the case, the presence of bacteria in the water bath is probably unimportant because there is no vehicle to convey them to the patient. However, the results of this study demonstrate a higher incidence of pneumonia in the patients using a heated-wire circuit. This may have occurred due to our sample size or to the growth of bacteria in the chambers, which we believe to be less likely. In addition, a statistically significant greater number of patients in the HWC group had tracheostomies (14% vs 7%, $p < 0.001$). This group of patients may have been at greater risk of pneumonia due to the need and presence of a tracheostomy. A larger study comparing HWC to NHWC may be in order to clarify this trend.

Cost comparisons are shown in Table 4. The cost efficiency of devices changes significantly when ventilator circuit-change intervals are lengthened to once per week. For 24 hours of ventilatory support, it is clear that the HCH is cost efficient. The circuit and device are cheaper, and practitioner maintenance time is reduced. At the end of 5 days, the cost difference/day between HCH and HWC shrinks to $4.27. As the HWC is used for a longer period of time, the initial high cost of the circuit is minimized. In addition, a new HCH is required every day, whereas a new 2-L bag of water for the HWC is required only every 48 to 60 hours. Increased costs with the NHWC are caused by a more frequent use of water ($3.51 per 2-L bag) and increased practitioner maintenance. With time, NHWC costs are also reduced, but not nearly to the extent that HWC costs fall.

Reductions in cost of humidification devices are modest, but measurable. According to a 1991 paper by Kacmarek,[28] 1,523 patients were ventilated for < 24 hours at the Massachusetts General Hospital. If we use equipment costs from Table 1, humidification costs for these 1,523 patients would be $3.23/day for an HCH, $24.95/day for a HWC, or $12.97/day for a NHWC. If an HCH rather than a HWC were used in half of these short-term patients, the cost savings in a year would be $16,539.78. If an HCH were used rather than a NHWC, the savings in a year would be $7,417.01. We strongly believe that the evidence for short-term use of HCH is persuasive. Use of an HCH in patients meeting the criteria in the algorithm is safe, effective, and cost efficient.

We believe that several limitations in our study may affect extrapolation of our results to other environments. The humidification techniques we used were all set to deliver a temperature and relative humidity less than 37° C and 100% relative humidity. It is unclear if setting the heated humidifier to temperatures of 37° C or higher would have changed the results. Interpreters of our results should keep in mind the humidifier settings utilized. We used an HCH with a moisture output of near 30 mg $H_2O$/L. We believe significantly different results may be seen with less efficient devices. We have already discussed the untoward effects of HME devices used in the ICU.[14-17] We also believe that the significantly higher number of patients with tracheostomy in the HWC (Group B1) may have influenced the incidence of nosocomial pneumonia, unrelated to the choice of humidification device.

### In Summary

The major findings of this study are:

- Use of an algorithm to match the appropriate humidification device to patient need is safe, effective, and cost efficient.
- An HCH is ideal for many surgical patients with no history of lung disease, who are adequately hydrated and require ventilatory support < 5 days. Our experience suggests that 67% of these patients can use an HCH safely and effectively.
- Use of an HCH in medical patients with a history of lung disease and secretion problems who are fluid restricted and require prolonged ventilatory support is apt to meet with failure. Our experience suggests that only 19% of patients in a MICU can use an HCH safely and effectively.
- Cost of humidification devices is a function of the required equipment, practitioner maintenance, and duration of use.

For 1 day of ventilatory support, use of an HCH is associated with significant cost savings compared to either HWC or NHWC.

We also believe the following are true:

- For patients requiring long-term support (> 5 days) a heated humidifier with a HWC is the device of choice, being both efficacious and cost efficient.
- Humidification devices, when properly cared for, do not influence the incidence of nosocomial pneumonia.

## ACKNOWLEDGMENTS

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# Evaluation of Four Analyzers Used To Monitor Nitric Oxide and Nitrogen Dioxide Concentrations during Inhaled Nitric Oxide Administration

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**BACKGROUND: The verification of nitric oxide (NO) doses and the measurement of nitrogen dioxide ($NO_2$) levels are essential in evaluating physiologic response and ensuring safe delivery during inhaled NO therapy. We conducted a 2-part evaluation of 4 NO-$NO_2$ analyzers: Pulmonox® II (PMX), Bedfont NOxBOX (BFX), Dräger PacII NO and 190 $NO_2$ (DRG), and Thermoenvironmental 42M (42M). METHODS: The analyzers were calibrated according to manufacturers' specifications. Part 1: 7 predicted NO concentrations [NO] ranging from 3 to 80 ppm were titrated into the main gas flow of a pressure-limited infant ventilator connected to a test lung and set in the IMV mode at a frequency of 30 breaths/min, PIP/PEEP of 30/5 cm $H_2O$, $T_I$ of 0.06 s, and $F_{IO_2}$ of 0.30, 0.60, and 1.0. Each analyzer was studied independently and NO-$NO_2$ levels were recorded after 5 minutes of stabilization. Measurements were repeated 3 times, and mean values were used for statistical analysis. Measured NO levels were compared to predicted [NO]. Part 2: The study was repeated using 5 predicted $NO_2$ concentrations [$NO_2$] ranging from 1 to 8 ppm, at an $F_{IO_2}$ of 0.21. Measured $NO_2$ levels were compared to predicted [$NO_2$]. RESULTS: Part 1: The bias ± precision values were: PMX −0.06 ± 1.13 ppm, BFX −0.67 ± 0.34 ppm, DRG 1.48 ± 1.09 ppm, and 42M −1.10 ± 1.11 ppm. $NO_2$ levels differed among the 4 analyzers. The BFX and 42M measured significantly higher $NO_2$ levels than the PMX and DRG ($p < 0.001$). Part 2: The bias ± precision values were: PMX 0.16 ± 0.75 ppm, BFX −0.29 ± 0.25 ppm, DRG 0.39 ± 0.33 ppm, and 42M −0.10 ± 0.25 ppm. CONCLUSIONS: NO measurements compared favorably to predicted [NO] with the 4 analyzers and are suitable for clinical use. All 4 analyzers provide precise $NO_2$ readings in a mixture of room air and $NO_2$ but provide different $NO_2$ readings in a gas mixture of $NO_2$ with $O_2 > 0.21$. The PMX and DRG are mainstream analyzers and the BFX and 42M are sidestream. The difference in sample technique may account for the difference in $NO_2$ readings across these 4 analyzers.** [Respir Care 1996;41(9):817-825]

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## Introduction

Inhaled nitric oxide (NO) is a potent and selective pulmonary vasodilator[1] that is being administered in the United States under experimental protocols. Therapeutic and diagnostic applications of inhaled NO have been reported in the management of persistent pulmonary hypertension of the newborn (PPHN).[2,3]

congenital heart disease (CHD),[4,5] and acute respiratory distress syndrome (ARDS).[6-8]

Inhaled NO readily diffuses from the alveolar space into the adjacent vascular smooth muscle and causes relaxation.[1] Nitric oxide's effect is confined largely to the pulmonary vasculature because it avidly binds with hemoglobin and becomes inactive.[9] This results in selective pulmonary vasodilation without causing systemic hypotension.[1,9]

Potential side effects do exist during inhaled NO administration. The direct binding of NO with hemoglobin results in the formation of methemoglobin.[10] Inhaled NO has potential toxic effects on the lungs particularly as it undergoes further oxidation.[11,12] When NO is exposed to oxygen, nitrogen dioxide ($NO_2$) forms and has been shown to adversely effect pulmonary function in humans.[12,13] These potential toxic effects must be closely monitored during inhaled NO administration.

Inhaled NO has been delivered in conjunction with mechanical and manual ventilation, and with systems for spontaneously breathing patients.[14-16] The verification of NO doses and the measurement of $NO_2$ levels is essential in evaluating physiologic response and providing safe delivery during inhaled NO therapy.[16-19]

The measurement of NO and $NO_2$ concentrations typically has been achieved with electrochemical and chemiluminescence analyzers.[16,17,20] Electrochemical analyzers measure the migration of ions generated from the reaction between NO or $NO_2$ and an electrolyte solution contained within an electrode or fuel-type cell.[16,20] Chemiluminescence analyzers measure NO concentrations by a reaction involving ozone.[15,16,20] This reaction results in the release of a photon of light that is proportional to the concentration of NO.[20] Concentrations of $NO_2$ are indirectly measured in a secondary reaction.[16]

The purpose of our study was to evaluate the accuracy of 4 NO-$NO_2$ analyzers that have been used during inhaled NO administration.

## Methods

The 4 analyzers evaluated were: 3 electrochemical models, Pulmonox® II (PMX),* Bedfont NOxBOX (BFX), and Dräger PacII NO and 190 $NO_2$ (DRG); and 1 chemiluminescence device, Thermoenvironmental 42M (42M).

The PMX, BFX, and DRG analyzers were calibrated according to the respective manufacturers' specifications. The PMX and DRG sensors were placed in a custom calibration manifold, and the BFX analyzer utilized a calibration manifold provided by the manufacturer. With 1 L/min of calibration gas introduced into each calibration manifold, 25 cm $H_2O$ of constant positive pressure was generated. The zero points were established with a room-air gas source, the NO spans with a 25-ppm NO source balanced in nitrogen ($N_2$), and the $NO_2$ spans with a 10-ppm $NO_2$ source balanced with $N_2$.

The 42M underwent a 2-point calibration procedure according to the manufacturer's specification. Pure $N_2$ was used to establish the zero point and NO of 25 ppm balanced with $N_2$ was used to adjust the span. The 42M did not require a separate calibration for $NO_2$.

The NO tank regulator was purged prior to the calibration of each analyzer in order to minimize residual $NO_2$. Following the calibration, the 4 analyzers were again exposed to the calibration gases in order to verify that NO and $NO_2$ readings were stable.

Each analyzer was evaluated separately and placed in-line with the NO delivery system that is used during mechanical ventilation of infants in our institution.[14] NO doses are achieved with this delivery system by titration of NO from a source tank into the main gas flow of the ventilator.[14] NO was introduced at the ventilator outlet via a 12-inch connecting tube with a volume of 85 mL. This tube served as a mixing chamber for the NO and ventilator gases.

Two adapters were added to the end of the connecting tube and secured to the inlet of the humidifier. The first adapter accommodated the $O_2$ analyzer, and the second adapter conformed to the respective NO-$NO_2$ analyzer. The PMX and DRG sensors were placed directly in the gas flow, and the BFX and 42M received a sidestream sample. The BFX analyzer received a gas sample passively by positive pressure from the ventilator and the 42M aspirated the gas sample. The NO-$NO_2$ analyzers were placed at this site because the 4 manufacturers indicated that the analyzers are susceptible to damage and inaccuracy if exposed to humidified gases. A customized device affixed to the exhalation valve was connected to the central vacuum system, and exhaled gases were scavenged (Fig. 1).

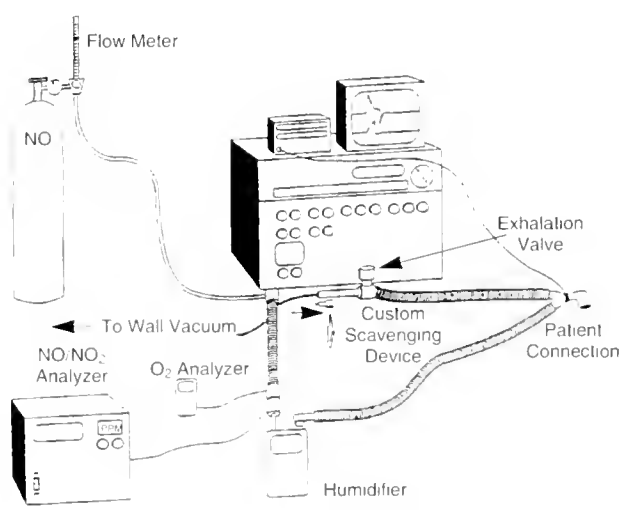


Fig. 1. Nitric oxide (NO) delivery via a continuous-flow infant ventilator. NO is titrated into the inspiratory limb of the ventilator upstream from the humidifier.

*Suppliers of commercial products are listed in the Product Sources section at the end of the text.

Part 1: NO concentrations were predicted from the equation

$$[NO] = (NO_{source}) \left(\frac{\dot{V}_{NO}}{\dot{V}_{Total}}\right),$$

where [NO] is the predicted or desired NO concentration, $NO_{source}$ is the concentration of the NO source tank, $\dot{V}_{NO}$ is the set flow from the source tank in mL/min, and $\dot{V}_{Total}$ is the total flow in mL/min and is the sum of the $\dot{V}_{NO}$ and the flow from the ventilator. Using this equation, we selected 7 doses of NO ranging from 3 to 80 ppm from an 800-ppm NO source (Table 1).

Table 1. Predicted Nitric Oxide Concentration [NO] with Various Flows from an 800-ppm Source of NO

| $\dot{V}_{NO}$ (mL/min) | $\dot{V}_{Total}$ (L/min) | Predicted [NO] (ppm) |
|---|---|---|
| 30 | 8.03 | 2.99 |
| 50 | 8.05 | 4.97 |
| 100 | 8.10 | 9.88 |
| 200 | 8.20 | 19.51 |
| 400 | 8.40 | 38.10 |
| 650 | 8.65 | 60.12 |
| 900 | 8.90 | 80.90 |

A standard oxygen flowmeter, calibrated in 100 mL/min increments, was connected to the NO regulator and used to titrate the $\dot{V}_{NO}$. A ventilator flow of 8 L/min was used and all flows were verified using a flow calibration analyzer. The flow calibration analyzer was adjusted to the density of room air for verification of NO and $NO_2$ flows. The ventilator, connected to a test lung (compliance = 1.0 mL/cm $H_2O$), was set in the time-triggered intermittent mandatory ventilation mode at a peak inspiratory pressure (PIP) = 30 cm $H_2O$ and a positive end-expiratory pressure (PEEP) = 5 cm $H_2O$, rate = 25/min, and inspiratory time ($T_I$) = 0.6 s.

Each [NO] was titrated into the ventilator circuit and at settings for fractional concentrations of delivered $O_2$ ($F_{DO_2}$s) of 0.30, 0.60, and 1.0. The analyzers were placed in-line separately, and NO and $NO_2$ measurements were recorded after 5 minutes of stabilization. This was repeated 3 times for each analyzer.

Digital measurements of ventilator settings and graphic display of $\dot{V}$, proximal airway pressure, and tidal volume ($V_T$) were observed and recorded throughout the study. Measured $F_{DO_2}$ was also observed and recorded.

The mean values for each set of NO and $NO_2$ measurements were determined and used for statistical analysis. The comparison of measured NO and [NO] was evaluated by using both the correlation coefficient and paired *t* test. Additional statistical analysis including bias (the mean difference between measured NO and [NO]), precision (the 95% confidence interval for the bias), and the limits of agreement (bias ± 2 SD) were determined. This additional analysis further assesses the degree of agreement between measured NO and [NO] and is based on the statistical methods described by Bland and Altman.[21] For each analyzer, the biases of the NO measurements for each $F_{DO_2}$ were compared using 1-way ANOVA. The $NO_2$ measurements were also compared between analyzers utilizing a 2-way ANOVA.

Part 2: During the first series of evaluations, we noted a large discrepancy in $NO_2$ readings among all 4 analyzers. Because of this discrepancy, we conducted a second test to verify the accuracy of these analyzers using known concentrations of $NO_2$.

The $NO_{source}$ was replaced with a $NO_{2\text{-source}}$ equipped with a flowmeter calibrated from 1-15 L/min. Five $NO_2$ concentrations ranging (1-8 ppm) from a 10-ppm $NO_2$ source were titrated into the delivery system described in Part 1.

The concentrations of $NO_2$ were predicted from the equation

$$[NO_2] = (NO_{2\text{-source}}) \left(\frac{\dot{V}_{NO_2}}{\dot{V}_{Total}}\right),$$

where $[NO_2]$ is the predicted $NO_2$ concentration, $NO_{2\text{-source}}$ is the concentration of $NO_2$ in the source tank in ppm, $\dot{V}_{NO_2}$ is the set flow in mL/min from the $NO_2$ source, and $\dot{V}_{Total}$ is total flow in mL/min and is the sum of the $\dot{V}_{NO_2}$ and the ventilator flow (Table 2).

Table 2. Predicted Nitrogen Dioxide Concentration [$NO_2$] with Various Flows from a 10-ppm $NO_2$ Source

| $\dot{V}_{NO_2}$ (mL/min) | $\dot{V}_{Total}$ (L/min) | Predicted [$NO_2$] (ppm) |
|---|---|---|
| 800 | 8.0 | 1.0 |
| 1600 | 8.0 | 2.0 |
| 3200 | 8.0 | 4.0 |
| 4800 | 8.0 | 6.0 |
| 6400 | 8.0 | 8.0 |

The same ventilator settings and monitoring were used, but with a $F_{DO_2}$ set at 0.21. Each analyzer was studied independently, and $NO_2$ measurements were recorded after 5 minutes of stabilization. The measurements were repeated 3 times for each analyzer.

The mean values for each set of 3 $NO_2$ measurements were established and used for statistical analysis. The comparison of measured $NO_2$ and [$NO_2$] was evaluated by using both the correlation coefficient and a paired *t* test. The bias, precision, and limits of agreement between measured $NO_2$ and [$NO_2$] were also determined as previously described in Part 1. Statistical analysis was accomplished with the use of a commercially available software package, with statistical significance defined as $p < 0.05$.

## Results

Part 1: A total of 63 NO and $NO_2$ samples were analyzed and recorded for each analyzer: 3 NO and $NO_2$ measurements at each of the 7 [NO] and at each of the 3 $F_{DO_2}$s.

Strong correlations were seen between the mean NO measurements and [NO] for all 4 analyzers: for PMX, r = 0.999; BFX, r = 1.0; DRG, r = 1.0; and 42M, r = 0.997. Despite these strong correlations, differences in the degree of agreement were observed between [NO] and NO measurements with all 4 analyzers (Table 3).

Table 3 Comparison of Measured NO with Predicted Concentration [NO] in ppm

| | Analyzer | | | |
|---|---|---|---|---|
| | PMX | BFX | DRG | 42M |
| Bias ± precision | −0.06 ± 1.13 | −0.67 ± 0.34 | 1.48 ± 1.09 | −1.01 ± 1.11 |
| Mean % bias | −0.2 % | −2.2 % | 4.7 % | −3.2 % |

Bias is the mean difference between predicted [NO] and measured NO levels and precision is the 95% confidence interval for the bias. The mean % bias is the average % difference between [NO] and measured NO levels ($p < 0.05$)

There was no significant difference between NO measured with the PMX analyzer and the [NO] ($p = 0.9$). The bias ± precision was −0.06 ± 2.49 ppm (mean percent bias = −0.2%), and the limits of agreement were −5.05 to 4.92 ppm. There was a tendency for measured NO to be slightly low when [NO] was < 20 ppm and slightly high when [NO] was > 60 ppm (Fig. 2). The difference between [NO] and NO measured with the BFX was statistically significant ($p < 0.001$) The BFX appears to underestimate the [NO] with a bias ± precision of −0.67 ± 0.34 ppm (mean percent bias = −2.2%). The limits of agreement were −2.16 to 0.81 ppm (Fig. 2). There was a significant difference between [NO] and NO measured with the DRG analyzer ($p = 0.01$). The measured NO levels tended to be higher with a bias ± precision of 1.48 ± 1.09 ppm (mean percent bias = 4.7%). The limits of agreement were −3.32 to 6.28 ppm with a tendency for the analyzer to measure higher NO concentrations when [NO] was > 40 ppm (Fig. 2). NO levels measured with the 42M tended to differ from the [NO] ($p = 0.07$). The measured NO was lower than the [NO] with a bias ± precision of −1.01 ± 1.11 ppm (mean percent bias = −3.2%). The limits of agreement were −5.88 to 3.87 ppm, with NO measurements being lower at [NO] of 40 and 80 ppm and higher at [NO] of 60 ppm and < 20 ppm (Fig. 2).

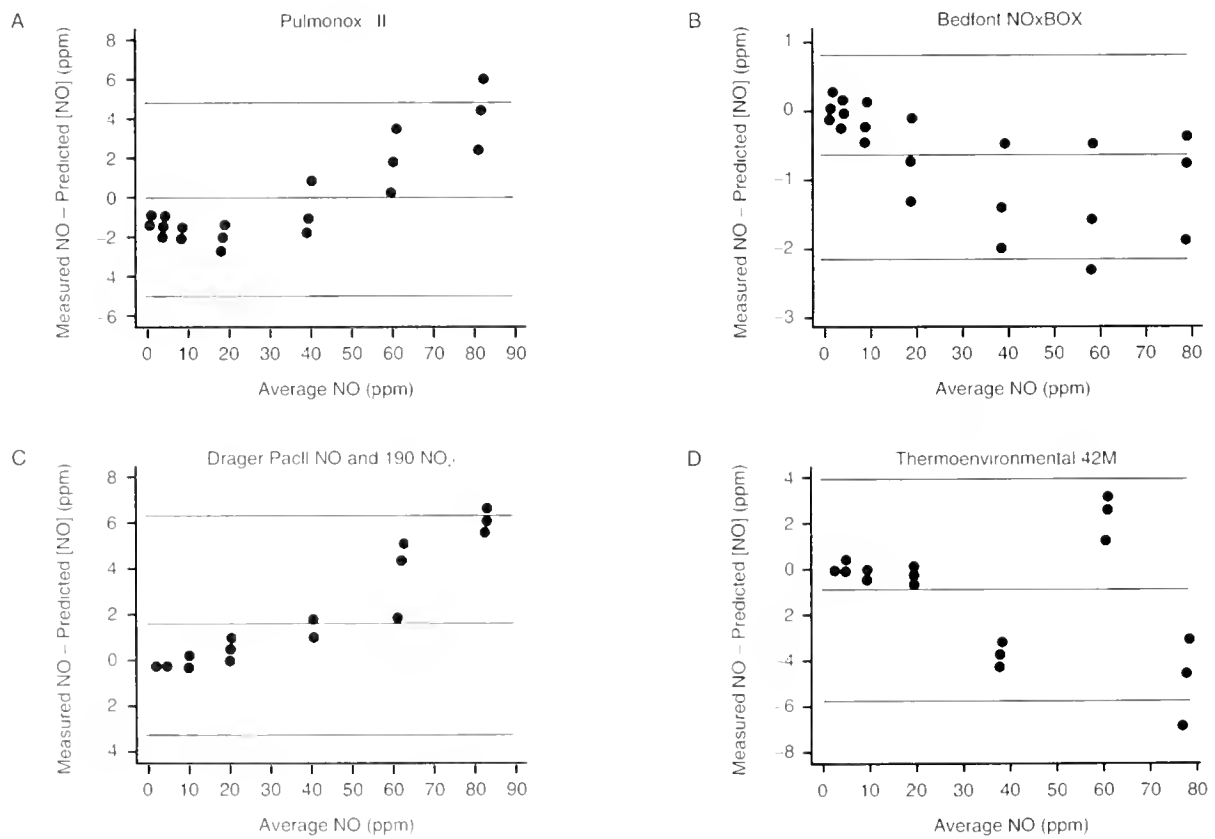


Fig. 2. The limits of agreement (bias ± 2 SD) of measured NO levels and predicted concentration [NO] in ppm. The difference between measured NO and predicted [NO] is plotted on the y-axis against the average NO (measured NO + [NO]/2) on the x-axis for: A. Pulmonox II; B. Bedfont NOxBOX; C. Drager Pacll NO and 190 $NO_2$; and D. Thermoenvironmental 42M.

As [NO] and $F_{DO_2}$ were increased, the $NO_2$ measurements increased with all 4 analyzers, but the degree to which $NO_2$ measurements increased differed among analyzers particularly at [NO] > 40 ppm (Fig. 3). The maximum $NO_2$ measurements were 0.70 ppm with the PMX, 3.07 ppm with the BFX, 1.33 ppm with the DRG, and 4.97 ppm with the 42M and were observed at the highest measured $F_{DO_2}$ of 0.92 and the highest [NO] of 80 ppm.

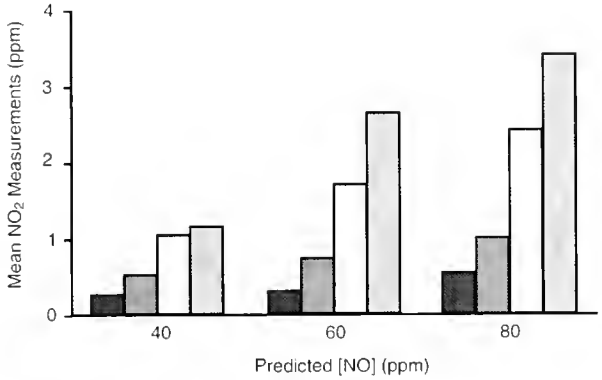


Fig. 3. $NO_2$ measurements at 3 predicted NO concentrations, or [NO]. Mean $NO_2$ measurements in ppm on the y-axis are plotted against [NO] in ppm on the x-axis. ■ = Pulmonox® II, ▒ = Dräger PacII NO and 190 $NO_2$, ▒ = Bedfont NOxBOX, and ▒ = Thermoenvironmental 42M.

The mean $NO_2$ measurements at [NO] of 40 to 80 ppm were 0.21 ppm to 0.54 ppm with the PMX, 1.0 ppm to 2.42 ppm with the BFX, 0.52 ppm to 0.98 ppm with the DRG, and 1.14 ppm to 3.39 ppm with the 42M (Fig. 3).

The mean $NO_2$ measurements obtained with the mainstream analyzers (ie, PMX and DRG) at [NO] of 40 ppm to 80 ppm were 0.37 ppm to 0.76 ppm. The mean $NO_2$ levels measured with the sidestream analyzers (ie, BFX and 42M) were 1.09 ppm to 2.91 ppm (Fig. 4). The sidestream mean $NO_2$ measurements were significantly higher than the mainstream measurements ($p < 0.001$).

Monitored ventilator settings remained stable throughout the study and the measured $F_{DO_2}$ decreased as [NO] was increased. The maximum measured $F_{DO_2}$ was 0.98 and occurred at the lowest $\dot{V}_{NO}$ of 30 mL/min or a [NO] of 3 ppm. The highest $\dot{V}_{NO}$ that was used was 900 mL, or a [NO] of 80.9 ppm, and resulted in a maximum measured $F_{DO_2}$ of 0.92.

For each analyzer, the biases for the NO measurements at each of the 3 $F_{DO_2}$s are included in Table 4. There were no statistically significant differences in the biases between each of the 3 levels of $F_{DO_2}$ with respect to the PMX, DRG, and 42M analyzers. There was a difference in the bias with the BFX analyzer, in which the bias decreased as $F_{DO_2}$ was increased. There was a statistically significant difference in the bias for a $F_{DO_2}$ of 0.30 versus 1.0 ($p = 0.01$), and, to a lesser degree, for an $F_{DO_2}$ of 0.60 versus 1.0 ($p = 0.05$).

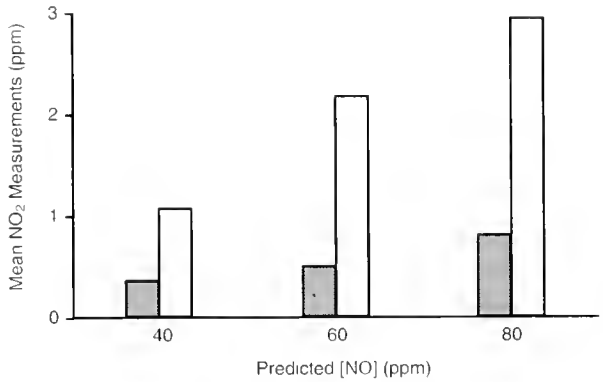


Fig. 4. Comparison of $NO_2$ measurements between mainstream analyzers (▒ = Pulmonox® II and Dräger PacII NO and 190 $NO_2$) and sidestream analyzers (▒ = Bedfont NOxBOX and Thermoenvironmental 42M). Mean $NO_2$ measurements in ppm are plotted on the y-axis against the predicted NO concentration [NO] on the x-axis.

Table 4. Biases of NO Measurements in ppm at Each of Three $F_{DO_2}$s*

| | Analyzer | | | |
|---|---|---|---|---|
| | PMX | BFX† | DRG | 42M |
| Bias‡ at $F_{DO_2}$ 0.30 | −0.85 | −1.18 | 1.19 | −0.53 |
| Bias at $F_{DO_2}$ 0.60 | −0.19 | −0.69 | 1.57 | −0.89 |
| Bias at $F_{DO_2}$ 1.00 | 0.85 | −0.15 | 1.66 | −1.59 |

*$F_{DO_2}$ = fractional concentration of delivered oxygen
†$p < 0.05$.
‡Bias is the mean difference between predicted [NO] and measured NO levels in ppm.

Part 2: A total of 15 $NO_2$ measurements were obtained with each analyzer: 3 $NO_2$ measurements at each of the 5 [$NO_2$]. The mean values were determined for each set of 3 $NO_2$ readings and used in statistical analysis. Monitored ventilator settings remained stable throughout the study. The measured $NO_2$ correlated well with the [$NO_2$] for the 4 analyzers: for PMX, $r = 0.995$; BFX, $r = 0.999$; DRG, $r = 0.999$; and 42M, $r = 0.998$. The degree of agreement differed across all 4 analyzers (Table 5).

Table 5. Comparison of Measured $NO_2$ with Predicted Concentration [$NO_2$] in ppm

| | Analyzer | | | |
|---|---|---|---|---|
| | PMX | BFX | DRG | 42M |
| Bias ± precision* | 0.16 ± 0.75 | −0.29 ± 0.25† | 0.39 ± 0.33† | −0.10 ± 0.25 |
| Mean % bias | 3.8 % | −7.0 % | 9.4 % | −2.4 % |

*Bias is the mean difference between predicted [$NO_2$] and measured $NO_2$ levels and precision is the 95% confidence interval for the bias. The mean % bias is the average % difference between [$NO_2$] and measured NO levels.
†$p < 0.05$.

There was no difference between $NO_2$ measured with the PMX analyzer and the $[NO_2]$ ($p = 0.6$), with a bias ± precision of 0.16 ± 0.75 ppm (mean percent bias = 3.8%). The limits of agreement were −1.04 to 1.36 ppm with a tendency for measured $NO_2$ to be lower at $[NO_2] < 6$ ppm (Fig. 5).

The BFX analyzer measured $NO_2$ levels that were significantly lower than the $[NO_2]$ ($p = 0.03$). The bias ± precision was −0.29 ± 0.25 ppm (mean percent bias = −7.0%), and the limits of agreement were −0.70 to 0.11 ppm. Measured $NO_2$ was markedly lower when $[NO_2]$ was > 4 ppm (Fig. 5).

$NO_2$ levels were significantly higher than $[NO_2]$ when measured with the DRG analyzer ($p = 0.03$). The bias ± precision was 0.39 ± 0.33 ppm (mean percent bias = 9.4%), and the limits of agreement were −0.14 to 0.93 ppm. Measured $NO_2$ levels tended to be lower at $[NO_2] < 4$ ppm and higher at $[NO_2] > 6$ ppm (Fig. 5).

There was no significant difference observed between $NO_2$ measured with the 42M and $[NO_2]$ ($p = 0.3$). The bias ± precision was −0.10 ± 0.25 ppm (mean percent bias = −2.4%), and the limits of agreement were −0.50 to 0.30 ppm. There was a tendency for measured $NO_2$ to be lower at $[NO_2]$ between 4 and 6 ppm (Fig. 5).

## Discussion

An important technical consideration in the development of an inhaled NO delivery system is the ability to verify NO doses and measure $NO_2$ concentrations.[16,18,19] We have demonstrated that the NO measurements compared favorably to the predicted [NO] in the 4 NO-$NO_2$ analyzers. These analyzers are suitable for clinical monitoring because the differences between the measured NO and the predicted [NO] (mean percent difference = −0.2 to 4.7%) would not be clinically important in most applications of inhaled NO.

We observed that the difference between measured NO and [NO] with the PMX analyzer was low when [NO] was < 20 ppm and high when [NO] was > 60 ppm. This resulted in a small mean percent difference of −0.2% that was not statistically significant. When using this instrument we anticipate that the NO measurements would be overestimated when using [NO] > 60 ppm and underestimated when using [NO] < 20 ppm.

The BFX mean percent difference was −2.2% and consistently underestimated NO over the full range of [NO]. The

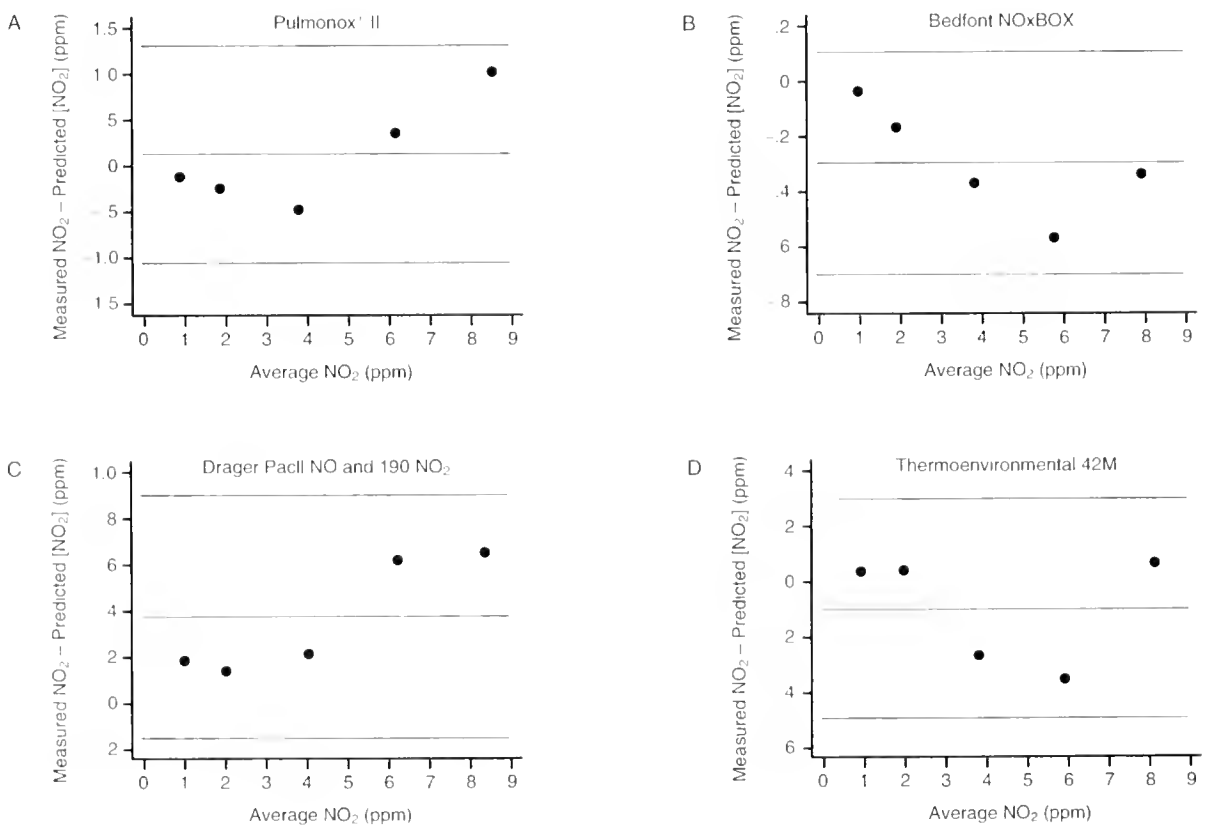


Fig. 5. The limits of agreement (bias ± 2 SD) of measured $NO_2$ levels and predicted $[NO_2]$ in ppm. The difference between measured $NO_2$ and predicted $[NO_2]$ is plotted on the y-axis against the average $NO_2$ (measured $NO_2$ + predicted $NO_2$/2) on the x-axis against: A. Pulmonox® II, B. Bedfont NOxBOX; C. Dräger PacII NO and 190 $NO_2$; and D. Thermoenvironmental 42M.

42M had a mean percent difference of −3.2%. NO measurements were underestimated at [NO] of 40 and 80 ppm and overestimated NO at [NO] of 60 and < 20 ppm. The mean percent difference with the DRG was 4.7% and similar to the PMX, overestimated NO measurements when [NO] was > 40 ppm.

The difference between NO measurements and predicted [NO] may be related to equipment calibration. Calibration linearity may not have been maintained at [NO] > 25 ppm, although each manufacturer reported that if recommended calibration procedures were followed, a stable linear relationship would be achieved up to 80 ppm of [NO]. Additional bias may have been introduced because the $O_2$ flowmeters are not calibrated to the density of NO, and the instrument used to verify the NO flows was adjusted to the density of room air.

Electrochemical analyzers may be susceptible to imprecision in the presence of positive pressure.[17] In 1 study in which 3 electrochemical analyzers were evaluated, the BFX and PMX were noted to have significant differences in bias as PIP and PEEP were increased.[22] It is possible that despite calibration under constant positive pressure, the electrochemical analyzers used in our study may have been sensitive to the pressure fluctuations of the ventilator (ie, PEEP to PIP).

The $F_{DO_2}$ may also influence the accuracy of these analyzers. Although not statistically significant, the bias for NO levels measured with the PMX appear to slightly decrease as $F_{DO_2}$ is increased, and the biases for the DRG and 42M tend to increase as $F_{DO_2}$ is increased.

The effect of oxygen on the bias for NO measurements was most evident with the BFX analyzer in which the bias decreased as the $F_{DO_2}$ was increased. In a similar study,[22] the bias of NO measurements was also observed to decrease as $F_{DO_2}$ increased. In this study, both the BFX and PMX were noted to have statistically significant differences in the bias of NO measurements as $F_{DO_2}$ was increased.

The differences between the [NO] and NO measurements with the 42M may be due to the phenomenon referred to as quenching.[16,20,23] Quenching occurs with chemiluminescence devices and results in the underestimation of NO and $NO_2$ due to the presence of water vapor and other gases, such as $O_2$ and $CO_2$.[16]

In one study[23] in which 2 chemiluminescence analyzers were evaluated, $NO_2$ measurements were underestimated by as much as 26%. The reaction chamber, which contributes to the estimation of $NO_2$ measurements, was constructed of stainless steel.[20] The conversion of $NO_2$ into NO in a stainless steel reaction chamber becomes interrupted, particularly in the presence of high oxygen concentrations, and results in underestimated $NO_2$ measurements.[26] Chemiluminescence analyzers, such as the 42M, can be equipped with molybdenum reaction chambers that greatly reduce the quenching effect of $NO_2$.[26]

Despite these potential sources for bias, all 4 analyzers performed similarly with respect to NO analysis and are reasonably precise.

In the first part of the study, we anticipated that the $NO_2$ measurements would increase as the [NO] and $F_{DO_2}$ were increased because the rate of oxidation of NO is determined by the concentration of $O_2$ and the square of the NO concentration.[21] We did not anticipate such a wide discrepancy in $NO_2$ measurements among analyzers. The discrepancy in $NO_2$ measurements was most evident at [NO] > 40 ppm. It is unlikely that a discrepancy in $NO_2$ measurements among analyzers would be observed if low NO doses (eg, < 40 ppm) are used. However, if higher NO doses are used, $NO_2$ measurements appear to be unreliable. At the highest [NO] and $F_{DO_2}$, the $NO_2$ measurements among the 4 analyzers ranged from 0.70 ppm to 4.97 ppm. We further demonstrated that the BFX and 42M analyzers yielded similar $NO_2$ readings and that they were significantly higher than the $NO_2$ measurements obtained with the PMX and DRG analyzers.

We conducted the second part of the study to determine whether the analyzers were accurate when compared to a predicted [$NO_2$]. In this part of the study, we demonstrated that the $NO_2$ measurements were similar in all 4 analyzers and correlated well with the predicted [$NO_2$] (mean percent bias −2.4 % to 9.4% ). This part of the study was conducted with a $F_{DO_2}$ of 0.21, and the effect on $NO_2$ measurements that a varying $F_{DO_2}$ would have is not known. We did not measure the $F_{DO_2}$, but assume that it was < 0.21 because of dilution from the $N_2$ balance in the $NO_2$ source tank. We speculate that the difference in the sampling technique is responsible for the difference in $NO_2$ measurements between analyzers. The PMX and DRG are mainstream analyzers, and the BFX and the 42M utilize a sidestream sampling design. It is likely that the sidestream sample line is a potential source for additional $NO_2$ production because of the additional contact time between NO and $O_2$. A longer contact time would result in a higher production of $NO_2$ and falsely high $NO_2$ values, particularly if a relatively large-volume sample tube and slow sample flow were used. A sample flow of 100 mL/min was used with both the BFX and 42M analyzers. The dimensions of the sampling tubing used were length 91.4 cm, internal diameter 1.5 mm, and volume 8 mL with the BFX, and length 92 cm, internal diameter 3.0 mm, and volume 14 mL with the 42M.

The objective of inhaled NO administration is to identify the lowest possible NO dose that results in the most favorable physiologic response. In our protocols, NO doses > 40 ppm typically are reserved for brief diagnostic trials, and doses < 40 ppm are used for prolonged therapeutic applications. Other studies have reported favorable responses utilizing NO doses < 20 ppm and in some cases as low as 100 parts/billion.[25,26] Despite the use of low NO doses, the need to monitor NO and $NO_2$ levels in NO delivery systems remains an important safety consideration.[16] Industrial standards for envi-

ronmental exposure limits are a time-weighted average of 25 ppm for NO and short-term exposure limits ranging from 1 to 5 ppm for $NO_2$.[27,28] A NO-$NO_2$ analyzer is required to detect any inadvertent changes in NO flows or other delivery system malfunctions that may result in over- or underdosing of NO and/or high $NO_2$ levels. Thus, the discrepancy in $NO_2$ measurements among these 4 analyzers, particularly at high NO doses is clinically important. If $NO_2$ measurements approach or exceed the recommended safe levels, there would be a tendency to decrease the NO dose or $F_{DO_2}$. If the sidestream analyzers provide falsely high $NO_2$ measurements, the NO dose or $F_{DO_2}$ may be unnecessarily decreased below the ideal therapeutic level. However, if the mainstream analyzers are underestimating $NO_2$ concentrations, the $NO_2$ levels may be approaching the limits of the recommended safe levels without the clinician's knowledge.

The 4 analyzers that we have evaluated are reasonably accurate and are suitable for clinical use, but some limitations may exist. The 42M and DRG are designed for environmental use and may require adaptations. We found the 42M chemiluminescence analyzer to be somewhat cumbersome and noisy, and it has no alarms.

The 42M, however, does contain an adjustable sampling rate that may provide a faster response time. Chemiluminescence models are currently the only analyzers that can measure NO in the parts/billion range and are used to verify NO cylinder concentrations.[18]

The [NO] can be predicted with our delivery system because it utilizes a continuous flow of gas.[14] This ability does not replace the need to verify the [NO] or measure $NO_2$. Institutions investigating NO therapy should evaluate the accuracy of their analyzers particularly if NO doses cannot be predicted. Additional factors that may influence the choice of analyzer include cost, portability, availability of alarms, and ease of use.

## Conclusions

We have demonstrated that NO measurements compare favorably to predicted [NO] with all 4 analyzers and are suitable for clinical use. All 4 analyzers provide precise $NO_2$ readings in a gas mixture of room air and $NO_2$ but provide different $NO_2$ readings in a gas mixture consisting of $NO_2$ and $O_2$ at a concentration > 0.21, particularly at [NO] > 40 ppm. The difference in sample technique may account for the differences in $NO_2$ readings in these 4 analyzers. Further investigation is required to identify the effect of sampling technique on $NO_2$ measurements with these analyzers.


## ACKNOWLEDGMENTS

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## PRODUCT SOURCES

**$NO/NO_2$ Analyzers:**

Pulmonox™ II Dual Nitric Oxide & Nitrogen Dioxide Analyzer, Pulmonox Medical Corp, Research & Development, Topfield, Alberta, Canada

NOxBOX Inhaled Nitric Oxide Therapy Monitor, Bedfont Scientific USA, Medford NJ

Drager PacII NO & 190 $NO_2$, Drager Inc, Pittsburgh PA

42M Chemiluminescence NO-$NO_2$-NOx Analyzer, Thermoenvironmental Instruments, Franklin MA

**NO and $NO_2$ Gas Sources:**

NO & $NO_2$ Gases, BOC Gases, Murray Hill NJ

**Tank Regulators & Flowmeters:**

Classic 200 and Classic 1000 Oxygen Flowmeters, Timeter, St Louis MO

NO and $NO_2$ Regulators, Controls Corporation of America, Virginia Beach VA

**Flow Calibration Analyzer:**

Calibration Analyzer RT-200, Timeter Instrument Corp, Lancaster PA

**Ventilator:**

VIP Bird, Bird Products Corp, Palm Springs CA

**Oxygen Analyzer:**

MAX$O_2$, Ceramatec Analytical, Salt Lake City UT

**Test Lung:**

Neonatal Demonstration Lung Model, IngMar Medical, Pittsburgh PA

**Statistical Software:**

Stata, Stata Corp, College Station TX

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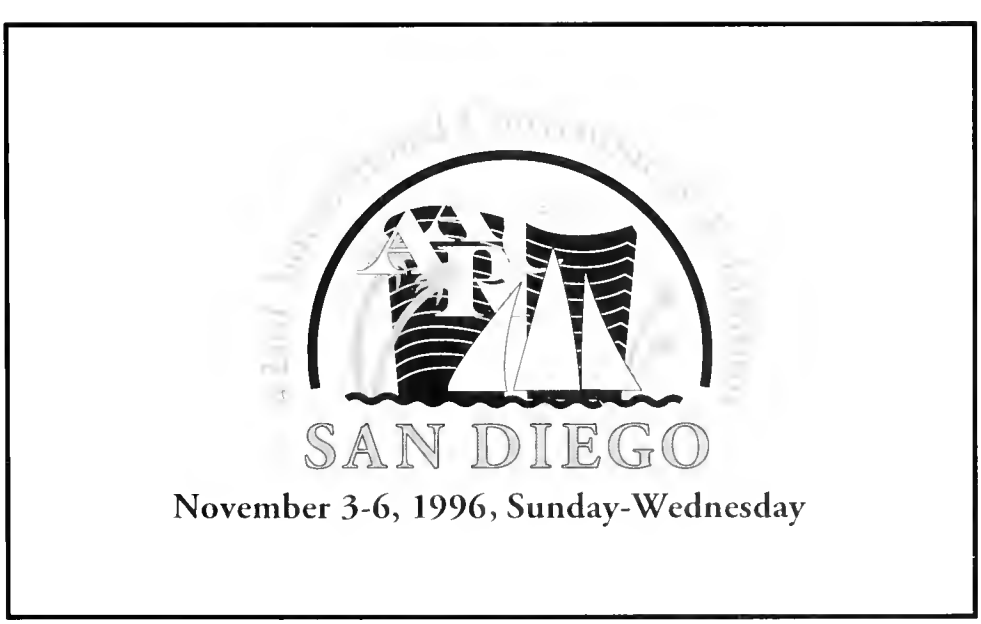

# End-of-Test Criteria in Spirometry: Zeno's Paradox Revisited

In the 5th century BC, the Greek philosopher Zeno of Elea posed the following conundrum: If, as we approach a destination, we keep closing the distance by half the original distance as we do, then how is it we ever arrive? Dubbed Zeno's paradox,[1] this line of thinking has come to epitomize the naysayer's view of reaching difficult-to-achieve goals. More than 2,000 years after Zeno first philosophized, spirometry was pioneered by Hutchinson in 1846[2] and now provides an occasion to revisit Zeno's paradox. Spirometry standards have been developed regarding criteria for acceptable equipment and for acceptable tests. Indeed, the most recent set of American Thoracic Society (ATS) standards became available in September 1995.[3] The standards retain older criteria for an acceptable start of test, namely extrapolated volume less than 5% of forced vital capacity (FVC) and no cough in the first second of expiration, and slightly modified criteria for an acceptable end of test, namely expiration lasting at least 6 seconds with a subsequent expiratory plateau lasting at least 1 second, or in the absence of an adequate expiratory plateau, expiration lasting 15 seconds. Modern-day Zeno's have wondered about the latter end-of-test criterion, about whether it is harmful to exhort patients to "Blow, blow, blow, blow, blow!" for 15 seconds, and even about whether achieving this end-of-test criterion is possible in patients with marked airflow obstruction.

Our purpose in this Point-of-View paper is to examine whether achieving the 15-second expiratory time end-of-test criterion is reasonable and, if so, to consider available spirometric techniques to increase the likelihood of achieving this goal. Our interest in this issue has been riveted by our participation as a Clinical Center in the National Institutes of Health-sponsored Registry for Patients with Severe Deficiency of Alpha 1-Antitrypsin.[4] In this natural history study, we have serially tested 48 participants with severe alpha 1-antitrypsin deficiency. Those participants had a baseline forced expiratory volume in the first second ($FEV_1$) that was 40.0 (27.8)% of predicted (mean, SD). The specter of Zeno appears to us every time we attempt to meet the stringent quality demands of this Registry while testing patients with severe airflow obstruction.

Indeed, the difficulty of achieving a 15-second expiration in a subject with severe airflow obstruction has been realized since the current end-of-test standards were first promulgated in 1987.[5] In an attempt to exorcise the specter of Zeno and to comply with end-of-test standards, pulmonary clinicians have sought ways to reach this difficult goal. In our pulmonary function laboratory, we first gained insight into ways to increase the likelihood of satisfying an end-of-test criterion while testing a 65-year-old man with severe emphysema, who surprisingly achieved a 20-second expiration. When asked about the key to his success, he divulged that the technician could not tell if or when he "backed off" on his effort as long as he waited until a few seconds into the maneuver to do so. Zeno be gone! Might not dynamic airway compression and "negative effort dependence" be hampering the ability of subjects to sustain an expiratory effort?[6,7]

To examine this hypothesis and to develop a strategy to improve achieving end-of-test criteria, we undertook a randomized crossover study of 2 expiratory strategies in 48 individuals with spirometry results that ranged from normal to severe airflow obstruction. We found[8] that the rate of achieving an acceptable end-of-test criterion for the overall group was 19% when the standard technique was used and 58% with a modified technique, in which the subject was encouraged to relax the expiratory effort after the first several seconds of exhaling. The longest expiratory times increased from an average of 13.3 to 19.7 seconds. The longer expiratory times also yielded larger FVCs for the more obstructed patients. Severely and moderately obstructed patients produced an FVC that averaged 300 mL higher when the modified technique was used. No clinically important differences were found for midflow ($FEF_{25-75\%}$), peak expiratory flow (PEFR), or $FEV_1$. More specifically, the prolonged expiratory times and larger FVC values were achieved without decreasing $FEV_1$. Even beyond the advantage of more often satisfying end-of-test criteria, the modified technique was favored by patients for being more comfortable than the standard blow, blow, blow, blow technique. Even such inveterate skeptics as Zenophiles must concede the advantages of a simple technique that succeeds more often with fewer side effects and greater patient satisfaction.

As confirmation of the value of this new expiratory strategy for spirometry, Moriyama and colleagues[9] subsequently

reported their experience with this technique in a series of 11 patients with severe alpha 1-antitrypsin deficiency resulting in severe airflow obstruction (mean $FEV_1$ 1.00 [0.4] L). These investigators evaluated 3 different expiratory strategies: (1) the traditional method in which the patient exhales as hard as possible for as long as possible, (2) the modified technique deseribed, and (3) a submaximal technique, in which the subject is instructed to blow rapidly but without maximal effort, for as long as possible. These investigators concluded that the traditional method produced reduced FVC values, less frequent satisfaction of ATS end-of-test criteria, and in 1 patient, an episode of syncope. In contrast, the modified method produced significantly longer expiratory times and greater values of FVC (compared to the traditional method). Also, all patients were able to meet an ATS end-of-test criterion using the modified technique. Unlike the other expiratory strategies, the submaximal method produced longer expiratory times and higher FVCs, but the $FEV_1$, $FEF_{25-75\%}$, and PEFR exhibited unacceptable variation.

As an extension of this study, we wondered about changes in transpulmonary pressures that accompany this modified technique. To assess these pressures, we asked 4 subjects with severe airflow obstruction, with a mean $FEV_1$ of 37(6)% of predicted, to undergo placement of an esophageal balloon for measuring intrathoracic pressures and to perform both standard and modified spirometry efforts. Our results show that during the standard spirometry maneuver, transpulmonary pressures peak between 70 and 100 cm $H_2O$ [6.87-9.81 kPa] at the start of the forced exhalation and are sustained at levels of around 40-50 cm $H_2O$ [3.93-4.91 kPa] until just before the end of the maneuver. During the modified technique, the transpulmonary pressures look identical to those obtained with the standard technique until the command to "Relax and push gently" is given. At that point, pressures fall to approximately 10 cm $H_2O$ [0.981 kPa] and are sustained at that level for the remainder of the exhalation. As a possible explanation for patients' subjective preference for the modified technique, the lower sustained transpulmonary pressures would be expected to impair venous return less, thereby preserving cardiac output and cerebral blood flow and minimizing lightheadedness.

Disgruntled by the ability to actually achieve a difficult-to-reach goal, disciples of Zeno may skeptically ask: "So what? Is there benefit in achieving a 15-second expiration and what difference does it make to do so using the modified technique?" In longitudinal epidemiologic studies, achieving end-of-test criteria consistently would permit serial comparison of values for $FEV_1$/FVC and FVC. In contrast, if subjects have significant airflow obstruction and continue to accumulate exhaled volume for each second of expiration up to 15 seconds but do not achieve a standard expiratory time, then the magnitude of $FEV_1$/FVC and of FVC will vary for technical reasons alone. Since our initial report about the modified expiratory technique,[8] we have adopted the new expiratory technique with one modification. We consider 15 seconds to be both a reasonable goal and a sensible end point for the exhalation. We continue coaching the subject to exhale and now provide periodic updates to the subject on how much longer before the exhalation should stop. While using the modified technique with this extra coaching, we have examined the relationship between FVC and the slow vital capacity (SVC) obtained on the same patient in 639 randomly selected patient records.[10] In this experience with the modified spirometry technique, the FVC equaled or exceeded the SVC (by more than 5%) in 536 instances (83.9%). By informing the subject how much longer is needed to sustain exhalation, we provide a psychological 'light at the end of the tunnel,' which encourages attaining 15 seconds of exhalation more than the open-ended, "Keep pushing! Keep pushing!" that typically accompanies the SVC maneuver.

Overall, we believe that achieving spirometric end-of-test criteria is a reasonable and attainable goal, even in subjects with severe airflow obstruction. We describe a modified expiratory technique that we and others have found useful to enhance achieving end-of-test criteria and recommend this technique to others who, like Zeno at least a millennium before spirometry was developed, have struggled with difficult-to-reach goals.

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**Editor's Note:** The authors and the editor invite the expression of opposing positions (or the support of their position) as a formal Point of View or in Letters to the Editor.

## CORRECTION

Equation 17 and 18 in Appendix 1: Model Sequence and Equations in Granger WM, A SCoP computer model of steady-state gas exchange: evaluating the oxygen-tension-based indices of venous admixture [Respir Care 1996;41(7):585-594] were incorrect. The 5-equation sequence is listed here. We regret the error.

The following 5 equations describe the $O_2$ dissociation curve and are the first 5 of the 15 simultaneous equations:

$$P_{(Corr)} = P_{a(O_2)}(10^{Z}), \quad [14]$$

$$Z = 0.024(37-T) + 0.4(pH-7.4) + 0.06(\log[40]-\log[P_{a(CO_2)}]), \quad [15]$$

$$U = A1(P_{(Corr)}) + A2(P_{(Corr)})^2 + A3(P_{(Corr)})^3, \quad [16]$$

$$S_{a(O_2)} = \frac{U}{1+U}, \text{ and} \quad [17]$$

$$C_{a(O_2)} = (1.39[Hb])(S_{a(O_2)}) + (B)(P_{a(O_2)}). \quad [18]$$

where $P_{(Corr)}$ = the corrected $P_{a(O_2)}$ based on pH, T, and $P_{a(CO_2)}$; Z = correction factor for causes of shifts in the oxygen dissociation curve, $S_{a(O_2)}$ = oxyhemoglobin saturation; and B = 0.0031, a constant for dissolved $O_2$.

# Books, Films, Tapes, & Software

**Comprehensive Respiratory Care**, by DR Dantzker, NR MacIntyre, ED Bakow, with 74 contributors. Hardcover, 1,308 pages, illustrated. Philadelphia: W B Saunders Company, 1995. $60.95.

Three months before I was asked to review **Comprehensive Respiratory Care,** it had already influenced my practice. I had purchased it a few months before in the exhibit hall at the California Society's annual meeting. Impressed by the noted editors and authors and by the comprehensive and sophisticated approach of the text, I had not been able to resist the purchase.

One day this spring, while visiting an affiliated rehabilitation facility, I was asked to recommend the respiratory care for a tetraplegic patient with left lower-lobe pneumonia and respiratory failure. I infrequently care for spinal cord injury patients, so I consulted my new resource. Chapter 48, "Neuromuscular Disorders," contains a useful survey of cervical cord injuries and discussions about "quad" cough, abdominal binders, phrenic nerve pacing, mask ventilation, and the use of resistive inspiratory exercises. During our discussion at the bedside, positive expiratory pressure (PEP) therapy was suggested as an intervention for the tetraplegic patient, but no one knew whether the patient was capable of active exhalation or which expiratory muscles were responsible. However, the answer, with the necessary citation, is there in Chapter 48.

Chapter 3, "Respiratory Muscles," contains serviceable information on static and dynamic respiratory muscle testing plus descriptions of respiratory muscle training methods. The authors expound on this in further detail in Chapter 50, "Pulmonary Rehabilitation." And, they supply considerable discussion of PEP therapy in the chapter entitled, "Bronchial Hygiene." **Comprehensive Respiratory Care** proved an effective and efficient reference.

Weighing in at 7 pounds, this first edition, green-bound treatise is hefty. There are 62 chapters arranged in 5 sections:

I. Anatomy & Physiology
II. Diagnostic Techniques
III. Therapeutic Techniques
IV. Clinical Problems
V. Respiratory Therapy Department Management

There are 26 chapters within the Clinical Problems section that deal with such topics as congestive heart failure, obstructive lung disease, atelectasis, and gastrointestinal emergencies. The first 4 sections are clinically focused and comprise 88% of the text pages.

Section V, "Respiratory Therapy Department Management," accounts for the remaining 12% of the text. At first, this section seems a bit out of place, stuck at the end of an exhaustive and authoritative list of physiologic and clinical chapters. But these chapters too are current, progressive, informative. They also present less obvious managerial topics such as ethics, staff and patient education, research and statistics, and the legal aspects of clinical care.

The 3 editors and contributing authors are well known in the field. David R Dantzker MD is Professor of Medicine at Albert Einstein College of Medicine, New York, and is well recognized for publications on oxygen delivery and utilization. Neil R MacIntyre MD, Associate Professor of Medicine, Duke University Medical Center, Durham, North Carolina, frequently publishes and lectures on mechanical ventilation and weaning. Eric D Bakow, MA RRT, is Director of Respiratory Care at the University of Pittsburgh and has been a member of the Clinical Practice Guidelines Committee for Bronchial Hygiene.

When one buys a text with such eminent editors, the extent to which they actually author the text is significant. In this case, authorship is as follows: Dantzker, 8 chapters; MacIntyre, 4 chapters; Bakow, 3 chapters. There are 71 additional contributors from various specialties—many names are familiar to me. Analysis of the contributors reveals 48 (65%) physicians, 16 (22%) therapists, and, the remainder, doctors of philosophy, registered nurses, attorneys, and others.

In the preface, the editor-authors state that because respiratory illness is rarely confined to lung dysfunction alone, patient care involves many professionals from various disciplines; and, thus, respiratory care is increasingly complex. Therefore they assert that it is their purpose to expand the scope of **Comprehensive Respiratory Care** beyond that of the traditional respiratory care textbook—to make it useful to practitioners from all disciplines and relevant to daily practice.

My first impressions of this work, while thumbing through it at the publisher's exhibit booth, still hold true after in-depth review, and are consistent with the authors' stated goals. This text 'gets down to business,' it's not a primer; it's a comprehensive, academically focused reference to respiratory care diagnosis and treatment.

The page layout testifies to this immediately. Pages are packed from border to border with information. Margins are filled with instructive notes. Helpful listings of key terms are placed at the beginning of each chapter. This effectively serves as a search aid when looking for new concepts—a nice feature for a reference source. Here, too, one will find an effective learning aid in the frequent, concise summary statements of important points.

The text itself is robust but reads easily. Throughout, there is consistent and correct use of American Thoracic Society and Système International abbreviations and terms. The eye navigates the page conveniently; chapter titles and subsections are alternately listed at the top of each page. Chapter topics and subtopics are clearly delineated within the text in boldface headings. And, because I 'highlight' as I read, I appreciate the publisher's use of heavier paper, which prevents bleed through.

Contributing to the fullness of each page is the ubiquitous and effective use of exceptional figures, illustrations, photographs, diagrams, and tables. These pictorial or summary elements are as important, if not more so, as the text. Each has the power to convey concepts that may have taken paragraphs or pages. The chapter, "Airway Management" is exemplary. It contains numerous photographs of cadaver-airway anatomy, both sagittal and laryngoscopic views, that demonstrate instrumentation and airway maintenance. The chapter, "Respiratory Muscles," contains a rare photo of the vascular supply of the diaphragm. In "Tissue Oxygen Delivery" an innovative figure illustrates how human energy needs are met by the environmental cycle of oxygen. Throughout the management chapters, diagrams represent key principles. The book also contains

invaluable tables. The quality and use of these elements distinguishes the text. (My one problem with the figures and tables is that many are positioned askew of page center—specifically those on Pages 99, 132, 134, 283, 343, 379, 544, 545, among others.)

With 74 contributors, 62 chapters and 1,308 pages, the text also contains some problems. For example, "Barotrauma in Mechanical Ventilation" (Chapter 34) is an acceptable but obligatory treatment of the topic. This chapter repeats the traditional mantra regarding the importance, indeed the pre-eminence, of peak inspiratory pressure (PIP) in this process. There is little development of the more current conceptualizations of this process: alveolar overdistention (volutrauma), shearing forces, and the importance of distinguishing PIP from peak alveolar pressure as monitored by plateau pressure. (The putative virtues of inverse ratio ventilation are even touted without presenting these distinctions.)

This newer synthesis of the barotrauma literature, with its shifted focus regarding mechanical ventilation management was, after all, summarized in the 1993 ACCP Consensus Conference on Mechanical Ventilation.[1] But I found it more interesting that most of these concepts are briefly presented in another chapter subsection of the text—Page 448, Chapter 22. Therefore, one could miss the latest information on barotrauma after having read the chapter, "Barotrauma." (The problem here is the manner in which such comprehensive textbooks are necessarily compiled, ie, authors write their chapter(s) without ever actually reading "their" book.)

Case 1: In the chapter devoted to neonatal respiratory care (Chapter 54, Page 1,040), the authors describe how many authors have developed nomenclature and classification schemes for the description of mechanical ventilators. They list in Table 54-1 the classification scheme for their chapter, but they cite no reference. The classification scheme they present is Robert Chatburn's[2] the co-author of the final chapter in the textbook.

Case 2: Chapter 26, "Oxygen Therapy," presents a page-long (Page 512) description of the venturi mask. In the discussion of venturi masks, the authors state that they operate on the Bernoulli principle and then cite the following reference by R. Scacci, "Air entrainment masks: Jet mixing is how they work; the Bernoulli and Venturi principles are how they don't."[3] Chapter 55, (Page 1,096) "Prehospital Respiratory Care," also has a subsection about oxygen therapy wherein "air-entrainment masks" are discussed. Chapter 55 starts by reminding the reader that air-entrainment masks are "often incorrectly referred to as 'Venturi masks'"— Chapter 26 meet Chapter 55!

Case 3: "Oxygen Therapy" deals with another topic (Page 508) that needs updating: the adverse effects of supplemental oxygen in patients with chronic obstructive pulmonary disease. This section warns, in the traditional, obligatory manner, of the risk of blunting the chronic hypercapnic patient's respiratory drive with excessive supplemental oxygen. But a number of studies[4-6] have shown that minute ventilation and respiratory drive are frequently unchanged in these individuals—a point rarely, if ever, sufficiently detailed in oxygen therapy reviews. (After all, anything new on this topic is of interest.) Again, it is interesting that "Pulmonary Gas Exchange" (Chapter 6) broaches the point, but cites only one of several studies.

Chapter 21, "Bronchial Hygiene," describes 2 therapeutic approaches, postural drainage therapies and PEP; if concordant with the book's title, there might have been mention of newer therapies such as high-frequency chest wall oscillation, the flutter valve, or intermittent percussive ventilation. This chapter also repeats the broad clinical practice guideline definition of "postural drainage therapies" as being any therapeutic intervention designed to (1) mobilize secretions, (2) improve ventilation-perfusion matching, and (3) normalize functional residual capacity. With this definition, would not most "bronchial hygiene techniques," including PEP and the 3 omitted techniques, qualify as "postural drainage therapies?"

And finally in "Unconventional Support Techniques for Ventilation and Oxygen" (Chapter 24, Page 470) the technique, tracheal gas insufflation (TGI), is described, though not identified by name, within the subtopic "Apneic Ventilation and Oxygenation." (TGI has been more frequently described as an adjunct to mechanical ventilation.) Then in "Weaning Mechanical Ventilatory Support" (Chapter 39, Page 738), airway pressure release ventilation is renamed "spontaneously breathing during pressure-controlled inverse ratio ventilation." Neither of these newer techniques are indexed using the more common and original terms, a misleading omission. But more important, I say, give the originators their due.

All told, my concerns are only suggestions for the next addition. This text is more than worthy of purchase. Because it goes beyond the introductory text with comprehensive review of 36 clinical management issues by recognized experts, **Comprehensive Respiratory Care** is an important resource. It is distinguished by its academic focus. The fact that a number of familiar topics are reorganized in new and innovative ways is a worthwhile bonus. This text is right for any inquisitive clinician who faces the expanding scope of respiratory care in daily practice.

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**Asthma and Rhinitis**, edited by WW Busse and ST Holgate. Hardcover, illustrated, 1,488 pages. Cambridge MA: Blackwell Scientific Publications, 1995. $225.

The reported worldwide prevalence of and morbidity and mortality associated with asthma has been climbing dramatically during the last decade. This trend continues despite an enhanced awareness by the medical professionals who treat patients with this disease. While the incidence of rhinitis has been demonstrated to be on the rise in Europe, little has been studied about its

prevalence in the United States. Asthma and allergic rhinitis are closely linked, and it is only logical that this textbook examine their relationship to each other.

**Asthma and Rhinitis** was written at a time when profound expansion in the understanding of the pathophysiology of these processes was occurring. This book is testament to this fact. There are 19 sections and 108 chapters in this book. Some of the sections include: disease classification, epidemiology, anatomy, pathology, mast cells and basophils, eosinophils, neutrophils, lymphocytes, macrophages and monocytes, platelets, fibroblasts, epithelial cells, mediators in inflammation, role of allergens in the airways, physiology of the airway, smooth-muscle response, adult asthma, and pediatric asthma. Each section contains individual chapters that describe either asthma or rhinitis and their interrelationship.

The co-editors are recognized authorities on these diseases, and 191 noted authors from around the world have contributed to this publication. Each section's introduction and conclusion are buttressed by a wealth of current, well-documented, and detailed information—a template that allows the reader to study each chapter in a predictable and consistent manner.

Each topic is addressed in great detail. For example, in "Neuroanatomy of the Airways," found in Part II, Chapter 48, a great deal of effort is put forth to describe neuropeptides with a detailed description of immunoreactivity of the endothelium in endobronchial biopsies. The mechanisms and the relationship of neuropeptides to this inflammatory process are explored at length, and the chapter is well referenced. While this is useful information to the medical specialist, it may go beyond what a typical 2- or 4-year respiratory-therapy-trained graduate may want or need to know.

We noted few deficiencies; however, on Page 1,188, a graph that details dose-response curves on pulmonary function data is obviously out of alignment to the axes. We found it interesting that only 14 pages of this text are dedicated to the pediatric patient with asthma. This is curious because asthma is one of the most common chronic illnesses of childhood, affecting more than 3 million children in the United States.

The intended readership for this book is not the respiratory care practitioner (RCP). This is not to say that it may not be a useful reference for the inquiring therapist. However, it is readily apparent after scanning through the text, that the target audience is the medical student or specialist.

To say that this book is massive or all encompassing is an understatement. It is, perchance, the ultimate reference book for asthma and rhinitis. This textbook should be prominently displayed on the medical library shelf of every pulmonary and/or allergy and immunology department. Its usefulness as a reference cannot be disputed. We also suggest that, perhaps, this book should have been divided into, at least, 2 books. This suggestion is made in light of the cost (and weight—10 pounds) of the book. Although we heartily recommend this book as a reference, we suggest that the RCP may want to borrow a copy rather than purchase it.

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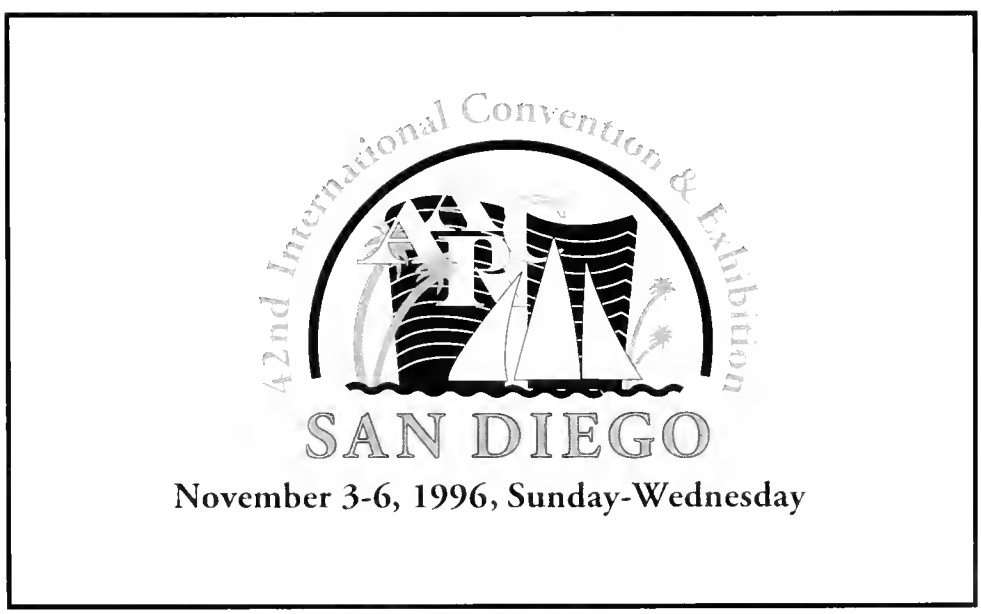

# Letters

Letters addressing topics of current interest or material in RESPIRATORY CARE will be considered for publication. The Editors may accept or decline a letter or edit without changing the author's views. The content of letters as published may simply reflect the author's opinion or interpretation of information—not standard practice or the Journal's recommendation. Authors of criticized material will have the opportunity to reply in print. No anonymous letters can be published. Type letter double-spaced, mark it "For Publication," and mail it to RESPIRATORY CARE, 11030 Ables Lane, Dallas TX 75229-4593.

## Helium-Oxygen Therapy for Asthma

A number of papers have reported the use of a helium-oxygen gas mixture (so-called heliox) as an adjunct to conventional treatment that may make intubation and ventilator support unnecessary in patients with severe asthma,[1-3] postextubation stridor,[4] upper airway tumor,[5] and respiratory failure from COPD.[6] We report briefly a case of severe asthma treated with heliox therapy in which intubation and mechanical ventilation were avoided.

A 19-year-old woman was admitted to the emergency department with severe dyspnea. Past medical history revealed chronic asthma, steroid use, and many exacerbations requiring intubation and mechanical ventilation due to respiratory failure. She had required tracheotomy with subsequent revision of the trachea 5 years earlier. At the time of presentation, the patient was alert but unable to speak in complete sentences. She was cyanotic, nostrils were flaring, and her breathing was labored, with respiratory rate of 40 breaths/min, blood pressure 104/60 mm Hg, pulse 155 b/min, and axillary temperature 98°F. Hemoglobin saturation by oximetry ($S_{pO_2}$), with the patient receiving oxygen at 6 L/min by nasal cannula was 92%.

Chest auscultation revealed marked expiratory and inspiratory wheezing bilaterally. Arterial blood gas analysis (ABGA) on arrival (2:30 PM) revealed pH 7.34, $P_{aCO_2}$ 45 torr, $P_{aO_2}$ 61 torr, $HCO_3^-$ 28 mEq/L, $S_{aO_2}$ 89%. She was treated with subcutaneous epinephrine, intravenous aminophylline, prednisolone, and nebulized albuterol treatment without improvement. Within 20 minutes, $S_{pO_2}$ dropped to 80%, and the patient exhibited stridor, increased nasal flaring, accessory muscle use, and restlessness. ABGA at 2:50 PM revealed a pH 7.31, $P_{aCO_2}$ 60 torr, $P_{aO_2}$ 48 torr, $HCO_3^-$ 29 mEq/L, $S_{aO_2}$ 79%. The patient was alert but in severe distress. She remained on a nasal cannula at 6 L/min and was placed on a nonrebreathing oxygen mask connected to an H cylinder of 70% helium-30% oxygen mixture at 12 L/min. (We estimated that in a proportional relationship, the nasal cannula at 6 L/min equals 44% $O_2$, diluting the helium to 56% but still providing a less dense mixture, reduction in turbulence, and lessened work of breathing.[7]) Within 20 minutes, the patient's respiratory rate dropped to 18 breaths/min, and $S_{pO_2}$ increased to 99%. She appeared calm and was able to speak in complete sentences, although she was surprised by her high pitched voice. We quickly reassured her that this was normal. At 3:10 PM, an ABGA on the helium-oxygen mixture revealed pH 7.39, $P_{aCO_2}$ 46 torr, $P_{aO_2}$ 180 torr, $HCO_3^-$ 27 mEq/L, $S_{aO_2}$ 99%. She remained on the helium-oxygen mixture for an additional 40 minutes, at which time it was discontinued without further incident. The patient was discharged from the hospital 6 days later.

At a time when health care is being challenged to provide quality care outcomes in a cost-effective manner, it becomes important to consider adjuncts such as helium-oxygen, which may help to avoid prolonged and costly care.

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# Reflecting on 40 Years of RESPIRATORY CARE:

## *Then:*

## Code of Ethics

The original Code of Ethics was written by Sister M. Yvonne
Revised November 18, 1959
American Association of Inhalation Therapists

### Preface

The professional calling of the Inhalation Therapist is the dedication of unselfish, loving, and intelligent service in treating conditions associated with respiratory pathology. An appointment to continue the work of healing which Christ began on earth, it is based on ethical values which have as an end the ultimate good of the whole person, regardless of race, creed, nationality, or economic status. These ethical values are set forth in a professional code based on the natural moral law which all members are obliged to observe. This demands personalities of intelligence and integrity further developed by education and professional training to a realization of rights and duties in regard to the profession, the physician, the patient, the employer, associates, and the public.

Although the private life of the Inhalation Therapist is not a proper matter for a professional ethical code, it must be remembered that no action, while on duty or off, can be divorced from the reputation of the profession as a whole.

### The Profession

1. The fundamental aim of the medical profession is, in all instances, to conserve life and promote health. The knowledge and services of the Inhalation Therapist must be used solely for the achievement of this aim.
2. Inasmuch as scientific research daily contributes to the improvement of methods, techniques, and materials, the Inhalation Therapist has the obligation to promote his professional competency through continued study, observation, and investigation.
3. Membership in the American Association of Inhalation Therapists indicates proper professional interest on the part of the Inhalation Therapist.
4. The Inhalation Therapist should maintain personal habits of grooming and conduct which are in keeping with a professional status thus inspiring respect and confidence.
5. The professional therapist holds in strict confidence all information of personal or private nature.

### The Physician

1. The Inhalation Therapist has the obligation of conscientiously implementing the physician's orders in the administration of Inhalation Therapy. The legal and professional responsibility rests with him.
2. The Inhalation Therapist has the obligation of providing the physician with intelligent, alert, and progressive service, in the sense of keeping up with the latest techniques.

### The Patient

1. The Inhalation Therapist renders service to the patient as one in need of professional ministrations; the therapist, therefore, transcends such things as ethnological, religious, and economic considerations.
2. In every relationship with the patient, the Inhalation Therapist should manifest a knowledge of human relations, demonstrating a spirit of kindness, gentleness, patience, and understanding sympathy.
3. The Inhalation Therapist is responsible for competently and efficiently administering the therapy prescribed.

### The Employer

1. The Inhalation Therapist should seek employment on the basis of professional qualifications only.
2. Contracts (written or oral) made by the Inhalation Therapist with the employer are to be fulfilled in letter and in spirit. Changing circumstances may justify subsequent requests for modification of the agreement.
3. The Inhalation Therapist may justly expect that statements regarding the quality of his work will not only be true but confidentially given and received by his employer.
4. The Inhalation Therapist has a right to a just remuneration for his services; acceptance of additional compensation is unprofessional.

### The Associates

1. The Inhalation Therapist should always be courteous to associates, according them understanding, help, encouragement, and loyalty; the therapist should be especially interested in the development of younger workers.
2. In the practice of the profession, the Inhalation Therapist should disclose procedures which are incompetent and dishonest to proper authorities; the therapist should at all times avoid unfavorable comment about associates to others.

### The Public

1. The Inhalation Therapist should realize that he has an obligation, by virtue of his citizenship, to the community as a whole. The therapist should conscientiously fulfill the duties of a citizen by participating in community planning and promotion of good public relations.
2. The Inhalation Therapist has an obligation to share the knowledge and skill of the profession with others who are working for the common good. The cause to be served must supersede the private good of the Inhalation Therapist.
3. Although an Inhalation Therapist should exercise the right to constructive criticism, he should be loyal to his profession, his organization, and his community.

**"Resolved that the following be added to the A.A.I.T. Code of Ethics:**

1. It is unethical for an Inhalation Therapist to profit financially from the sale of inhalation therapy equipment or supplies unless he is a recognized representative of that company;

2. It is unethical for an Inhalation Therapist to accept a gratuity in any guise whatever, wherein such gratuities might be interpreted as influencing sales of inhalation therapy supplies or equipment;

3. Instructional practices by a company or by representatives of a company for promotion of sales of their product, utilizing a subsidy, rebate, or gratuity to the student are unethical. An example of the latter may be the payment of expenses, in whole or in part, for travel or living." [Respir Care 1963;8(4):18-19]

*Now:*

# AARC Statement of Ethics and Professional Conduct

In the conduct of their professional activities the Respiratory Care Practitioner shall be bound by the following ethical and professional principles. Respiratory Practitioners shall:

- Demonstrate behavior that reflects integrity, supports objectivity, and fosters trust in the profession and its professionals.
- Actively maintain and continually improve their professional competence, and represent it accurately.
- Perform only those procedures or functions in which they are individually competent and which are within the scope of accepted and responsible practice.
- Respect and protect the legal and personal rights of patients they treat, including the right to informed consent and refusal of treatment.
- Divulge no confidential information regarding any patient or family unless disclosure is required for responsible performance of duty, or required by law.
- Provide care without discrimination on any basis, with respect for the rights and dignity of all individuals.
- Promote disease prevention and wellness.
- Refuse to participate in illegal or unethical acts, and shall refuse to conceal illegal, unethical, or incompetent acts of others.
- Follow sound scientific procedures and ethical principles in research.
- Comply with state or federal laws which govern and relate to their practice.
- Avoid any form of conduct that creates a conflict of interest, and shall follow the principles of ethical business behavior.
- Promote the positive evolution of the profession, and health care in general, through improvement of the access, efficacy, and cost of patient care.
- Refrain from indiscriminate and unnecessary use of resources, both economic and natural, in their practice.

[Revised, December 1994]

## RETROSPECTROSCOPE

# Speculation on Speculation

A legitimate public concern is how to speed up scientific discovery and its application to clinical medicine and surgery. Several years ago, I listed 18 steps between the initial idea and full clinical application and noted that delay *could* occur at any one of these (1). However, I ruled out one of these as a factor of importance—a scientist's indifference toward publishing his work for others to read. It is true that historically there have indeed been some notable delays between an initial discovery and its publication, especially in past centuries, when the author of a "breakthrough" was apt to be rewarded by burning at the stake instead of by the Nobel Prize; authors then had some understandable reluctance to publish at all. And in European scientific circles in the nineteenth and early twentieth centuries, we must confess that there was a curious phenomenon called "the sealed letter" (2). But in modern times, scientists seem to report their discoveries with either prudent or immodest promptness; the weight of *Index Medicus*, about 5 pounds per month, which prints only title, authors, and journal reference for each article, with not even a minuscule summary, is proof enough of authors' urge to publish for all to read, confirm, extend, apply, or deny.

However, if we're honest, we can't rule out all 18 steps. There *are* steps where speeding up might well be accomplished. One of these I've labeled "Publisher's Dawdle" (3). Another is getting newly published information to the next man along the line. One problem here may be not what's *in* the published article, but what's *not* in it. In the myriad of articles listed monthly in *Index Medicus*, what is usually *not* included is speculation—an author's ideas or suggestions reached by contemplation, reasoning, conjecture, or surmise but not yet supported by sufficient hard data to merit separate publication. I speculate that we might speed the advance of medical science by inviting all authors to include some speculation, labeled clearly as such in their scientific articles, to follow Introduction, Methods, Results and Discussion—and to precede and not to be confused with the author's well-fortified Conclusions. *Pediatrics* now does this by asking author's to include a paragraph headed "Speculation and Relevance, or Implications," but most journals frown on such a practice.

What does and does not qualify as reasonable, legitimate speculation?

(a) It should not be science fiction of the Tom Swift or Star Trek type (predictions of what the next century might bring). This would exclude Benjamin Franklin's 1749 speculation on his electrical cooker (in his April 29 letter to Peter Collison):

> It is proposed to put an end to them [electrical experiments] for this season, somewhat humorously, in a party of pleasure on the banks of Skuylkil. Spirits, at the same time, are to be fired by a spark sent from side to side through the river, without any other conductor than the water; an experiment which we some time since performed, to the amazement of many.
>
> A turkey is to be killed for our dinner by the electrical shock, and roasted by the electrical jack, before a fire kindled by the electrified bottle: when the healths of all the famous electricians in England, Holland, France, and Germany are to be drank in electrified bumpers, under the discharge of guns from the electrical battery (4).

On the other hand, Eadweard Muybridge's speculation might be acceptable since, in 1872, he had indeed invented motion pictures, and Edison a little later had put together a reasonably good phonograph. In 1898 Muybridge wrote, in the preface to his book *Animals in Motion:*

> The combination of such an instrument [motion pictures] with the phonograph has not, at the time of writing, been satisfactorily accomplished; there can, however, be little doubt that in the—perhaps not far distant—future, instruments will be constructed that will not only reproduce visible actions simultaneously with audible words, but an entire opera, with the gestures, facial expressions and songs of the performers, with all the accompanying music, will be recorded ... for the instruction or entertainment of an audience long after the original participants shall have passed away (5).

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His speculation became reality in 1927 with the production of "The Jazz Singer"; whether Muybridge's speculation ignited the spark of invention and development required for "talkies" is not known.

(b) The speculation can and should include fields completely outside the author's interest or competence, such as the 1896 suggestion that newly discovered X-rays be used to check passengers' luggage for concealed bombs, or a later suggestion that microvascular surgical technics might be used to reconstruct successfully a ligated vas deferens (when the owner had new plans that required an open duct), or the suggestion that an oral diuretic, designed for relieving patients with congestive heart failure of their excess fluid collections, might lower blood pressure in patients with essential hypertension.

(c) The speculation must not be an obvious next step in the author's continuing investigation if he has already bolstered his speculation by pilot experiments.

Adhering to this qualified definition, let's look into the Retrospectroscope and see what we can learn. We *cannot* learn how many investigators included speculation (useful or impractical) in their manuscripts because we can look only at what escaped the editor's scissors or blue pencil; however, we can look at some speculation that has been published and estimate its impact on the advance of medicine.

## Speculation with No Impact

### Extracorporeal Oxygenation

Hooke in 1667 wrote:

> I shall shortly further try, whether the suffering the Blood to circulate through a vessel, so as it may be openly exposed to the fresh Air, will not suffice for the life of an Animal; and make some other Experiments, which, I hope, will thoroughly discover the Genuine use of Respiration; and afterwards consider of what benefit this may be to Mankinde (6).

This, the first speculation on extracorporeal oxygenation of blood, predictably had no impact on medicine. Oxygen, microbiology, anticoagulants, blood groups, anesthesia, and modern surgery still had to be discovered. Extracorporeal oxygenation *did* become useful for organ perfusion in physiologic laboratories in the nineteenth century, but it is unlikely that this can be attributed to Hooke.

### The Stewart Clamp

In 1910, G. N. Stewart, a physiologist well known for his indicator-dilution principle, needed a device to occlude an artery only partially (for operations on its wall), permitting blood flow to continue through the remainder of the vessel. He described his clamp in the *Journal of the American Medical Association;* because he was not a surgeon, presumably he published it in a clinical journal only to call it to the attention of surgeons. He speculated freely for them:

> Such clamps might be employed to arrest hemorrhage from a wound in a large vessel which could not be clamped completely without detriment, and during the suturing of the wound; possibly in the treatment of sacculated aneurism in some situations; in performing lateral anastomosis of blood-vessels in cases where it is undesirable to completely occlude one or both of the vessels for the time required in the operation; in performing lateral implantation of one vessel on to another which must not be totally occluded; in inserting a cannula laterally into a vessel without stopping the circulation when there is no convenient branch of the vessel which might be used, or where it is disadvantageous to occlude such a branch; in narrowing experimentally the lumen of a vessel without temporarily occluding it, especially when a diminution of the lumen by a definite amount is desired, etc (7).

As far as I know, the first use of Stewart's clamp, 36 years later, was in 1946 when it became the Potts' clamp and was used to permit aorta-pulmonary artery anastomosis to relieve cyanosis in blue babies. Because Potts was unusually generous in giving credit to the work of Blalock and Taussig that preceded his operation, but never mentioned Stewart's clamp, I can only surmise that Potts never saw Stewart's article even though it was written in English and published in the *JAMA*.

### Freeze Drying

In 1909, Shackell, trying to measure accurately the glycogen content in liver and muscle of steers, ran into the problem of rapid postmortem hydrolysis of glycogen; to stop this hydrolysis, he devised a method of rapid freezing followed by vacuum desiccation. He realized that freeze-drying had wide applications to the preservation of sera, of other components of blood, of viruses (e.g., of rabies), and of food. He wrote:

> Experiments so far indicate that all material, especially those unstable substances associated with immunity work, can be desiccated as outlined and can be indefinitely preserved.
>
> It is generally recognized that no chemical changes take place in perfectly dry substances. The products of this method are for all purposes entirely moisture-free. Deterioration in them is therefore absolutely precluded, providing the ordinary precautions of stoppered containers are taken to prevent contact with atmospheric moisture. If necessary, substances after drying can be hermetically sealed *in vacuo*.

> The special value of the method in medicine lies undoubtedly in the field of serum-therapy. One of the great practical problems has been the prevention of auto-degeneration in serums and toxins. It has been found possible, however, by the use of this method to obviate autolysis of such typically unstable substances as the complement of guinea-pig serum and the virus of hydrophobia.
>
> Though but a few of the most important results of the method have been mentioned in the present paper, the writer and his colleagues appreciate the probability of its widely extended application to many current problems, several of which are being attacked at the present time (8).

Shackell wrote only one other paper on freeze-drying, dealing largely with preserving rabies virus. In these two papers, he tossed out enough ideas to excite basic and applied scientists, in universities and industry, for years to come. But (except for Gersh's use of it to prepare histologic sections in 1932) no one used the new method until 1935, and it had little application until World War II, when it became important in the large scale production of preserved dried plasma and penicillin. Finally industry applied it in the food business and among other things it led to the production of a best seller—instant freeze-dried coffee.

Why did Shackell's experiments and speculation go unnoticed for almost 25 years? Elser and co-workers (9) in 1935 wrote:

> Shackell fully appreciated the value of his discovery, particularly in the field of immunology, but apart from publishing a paper in association with Harris dealing almost entirely with the preservation of the virus of rabies, he apparently failed to continue this line of investigation and for some unaccountable reason his work did not receive the attention from immunologists which in our opinion it deserved. Possibly, the appearance of the original communication in the *American Journal of Physiology* not commonly consulted by bacteriologists and the fact that subsequent papers stressed the value method in connection with the conservation of rabies virus may be in part responsible for the lack of progress made in this field during the time that has intervened.

## Speculation with Impact

On the other hand, some speculation seems to have been picked up reasonably quickly by others, whose work then led to specific medical advances.

### Flame Photometry

Barnes in 1945 speculated on a wide variety of uses of this new technic: for continuous analysis of salts in water, for determination of sodium and potassium in soil samples, and in the analysis of biologic materials (10). Of the latter, he said:

> Some of the most interesting uses to which these instruments have already been put concern the analysis of biological materials. In the hands of several clinical research workers, the flame photometer has been used successfully to analyze such materials as whole blood, blood serum, urine, body fluids, and tissue residues. These analyses, which are usually both difficult and time-consuming as a result of the very nature of the samples and the small size of the average samples which are available, may readily be performed. For the determination of sodium in blood serum, a sample of as little as 0.1 mL can be satisfactorily analyzed after diluting by a factor of 1 to 100. The potassium content of serum could conceivably be determined on a 0.1-mL sample after diluting to 2.5 mL but a 0.5-mL sample is much to be preferred. This fact, plus the speed with which the analyses may be completed, makes possible certain studies which have hitherto been impossible.
>
> Thus, in the clinical laboratory, the flame photometer has proved itself to be a most valuable instrument in connection with research on metabolic studies, the rapid diagnosis, and the treatment of certain diseases.

Obviously, pilot studies had already been done but this paragraph (published in *Industrial and Engineering Chemistry*, a nonmedical journal) stimulated widespread use of the new instrument. By 1947, Hald had reported careful studies of $Na^+$ and $K^+$ in biologic materials and an important new tool was available for basic and clinical research and clinical diagnosis and care.

### Blood Oxygen Tension

Davies and Brink were primarily interested in measuring the $O_2$ consumption of nerves and sympathetic ganglia. To do this, they constructed an $O_2$ electrode that worked well in saline solutions. They dabbled a bit in measuring blood $P_{O_2}$ and ran into a few practical problems that they believed could be solved. Their main interests lay elsewhere but Brink did, in 1950 (11), offer this suggestion to others:

> The electrode was used for several experiments, but the agar plug finally became ineffective. The principal reason is that agar does not adhere firmly to a glass surface. Further development of electrode coatings is desirable. Other tests indicate that a collodion membrane is effective but can be used only where mechanical damage to the electrode tip is not likely to occur.
>
> The measurement of dissolved $O_2$ in whole blood seems of sufficient importance to warrant more development of these methods for this purpose. The platinum electrode has the distinct advantage over the drop-

> ping Hg type that it can be interested in the flowing blood of the experimental animal. In fact, by means of a motor-driven syringe it would be possible to draw blood from a human subject at a uniform rate and measure the dissolved $O_2$ therein. The flow rate could be as low as 3 cu mm/min, as in the flow respirometers used in this laboratory. *It is apparent that the component parts exist for successful development of an electrical instrument for measurement of dissolved $O_2$ in whole blood in situ. All that is required is an intensive program of development of the electrode for this specific purpose. Those interested in using the measurements must decide whether such a development is justified.* (Italics added.)

Leland Clark did have a specific need for such an electrode: he ingeniously solved the problem 3 years later (12). The Clark electrode was soon widely used in basic and clinical research and clinical care.

## Humoral Transmission of the Nerve Impulse

G. L. Brown attributes the beginnings of this novel concept to the speculations of T. R. Elliott in 1904. Elliott, after demonstrating that adrenalin secreted by the adrenal medulla does not directly stimulate either sympathetic ganglia or nerves, but does not excite *peripheral* tissue (e.g., smooth muscle) innervated by sympathetic nerves, speculated (13):

> Therefore it cannot be that adrenalin excites any structure derived from, and dependent for its persistence on, the peripheral neurone. But since adrenalin does not evoke any reaction from muscle that has at no time of its life been innervated by the sympathetic, the point at which the stimulus of the chemical excitant is received, and transformed into what may cause the change of tension of the muscle fiber, is perhaps a mechanism developed out of the synapsing sympathetic fibre, the function of which is to receive and transform the nervous impulse. *Adrenalin might then be the chemical stimulant liberated on each occasion when the impulse arrives at the periphery.* (Italics added)

Further advance waited for 10 years but then came in successive studies by Dale, Loewi, Feldberg, Brown, Gaddum, and Cannon, and opened whole new fields in physiology and pharmacology.

In 1948 Ahlquist speculated that Elliott's receptors were of two types, alpha and beta adrenoreceptors (13a); his predictions led to a search for agonists and antagonists (blockers) of beta receptors and to finding new drugs for treating arrhythmias and hypertension. It is of interest that Ahlquist's pharmacological manuscript was turned down by the *Journal of Pharmacology and Experimental Therapeutics* (too much speculation?) and was published in the *American Journal of Physiology*.

## Transfusion Reactions

Landsteiner in 1900 discovered that immunologically there were three different types of human blood (14). In that paper, he did not speculate that transfusion of blood of one type from a donor to a recipient whose blood was a different type might cause hemolysis or agglutination of red blood cells; transfusions continued without previous matching of blood, and so did transfusion reactions. But in 1907, Hektoen published a brief article in the *JAMA* (15) that contained no data but did contain the following speculation:

> By means of a refined technic Crile recently transfused blood from normal to diseased human beings, and with apparent success. The occurrence of isoagglutinins in human blood suggests that under special conditions homologous transfusion might prove dangerous by leading to erythrocytic agglutination within the vessels of the subject transfused. It has not been possible to conduct animal experiments on this point because of failure to demonstrate isoagglutinins in the serum of suitable animals. *It may be pointed out, however, that the possible danger here indicated can be avoided by the selection of a donor whose corpuscles are not agglutinated by the serum of the recipient and whose serum does not agglutinate the corpuscles of the latter* [italics added]; that is to say, donor and recipient should belong to the same group and preferably to Group I or II. The actual isoagglutinative relation of the donor and the recipient are readily determinable in a short time in the manner already outlined.

By 1911, Ottenberg introduced direct cross-matching of blood from donor and recipient, and transfusion reactions for the most part came to an end. When Hustin in 1914 made indirect transfusion possible by adding a new anticoagulant citrate, to blood, blood transfusions at last became a safe and practical therapeutic measure.

## The Cardiac Pacemaker

In 1951, Callaghan and Bigelow, like others before them, tried to pace an animal's heart with an electrode in contact with the natural pacemaker, the sino-atrial node; in their experiments, they tried to achieve this contact by passing an electrode down the superior vena cava. However, they noted that "from the practical aspect ... intimate contact with the sino-auricular node is not essential for good control since distances up to three quarters of an inch from the nodal area were adequate." They speculated that the time had come to apply this to the human heart beset by serious iatrogenic arrhythmias that occurred during intracardiac procedures (16).

Within a year, Zoll tried first an intraesophageal electrode and then subcutaneous needles (placed on opposite sides of the thorax) in man and successfully paced the human heart.

And eventually others used transvenous pacing of the human heart much as Callaghan and Bigelow had suggested from their work on animals.

## Nitrous Oxide and Ether Anesthesia

Humphry Davy in 1800 speculated that "As nitrous oxide in its extensive operation appears capable of destroying physical pain, it may probably be used with advantage during surgical operations in which no great effusion of blood takes place" (17). Davy's former pupil, Michael Faraday, wrote in 1818,

> In trying the effects of the ethereal vapour on persons who are peculiarly affected by nitrous oxide, the similarity of sensation produced was very unexpectedly found to have taken place. One person who always feels a depression of spirits on inhaling the gas, had sensation of a similar kind produced by inhaling the [ether] vapour (18).

Physicians did not immediately act on these suggestions. Whether they failed to read them or were fearful of using these gases or vapors (despite the incalculable benefits of a general anesthetic agent), we cannot say. But someone noted them, because "laughing gas" parties became pretty common thereafter. One adventurous group asked Dr. Crawford Long in 1842 to prepare some nitrous oxide for an evening's lark; he replied that he didn't have the apparatus for making the gas but he did have some ether and that would do the trick just as well. As a result of these parties and the obvious analgesia that ether or nitrous oxide conferred on those injured after falling, Long deliberately used ether for surgical anesthesia in 1842, and Colton and Wells used nitrous oxide in 1844.

## Thoughts on Speculation

I haven't done a systematic analysis of how many authors, in what periods of time and in what cultures, have speculated (beyond the facts on which they based conclusions or recommendations) and whether their speculation was right or wrong. Nor have I tried to determine numerically how many investigators were strongly influenced by earlier speculation of others and how long it took them to be so influenced. Accurate data on this are hard to obtain because the rigid, stereotyped format of today's scientific paper favors an author who would like to avoid acknowledging the source of his ideas or hypothesis.

However, of a random sampling of 50 articles* in which authors *did* speculate, only 4 proved later to be wrong. These were Sir Almroth Wright in 1894 on oral administration of citrate or calcium to influence blood coagulation in man (and since some of his colleagues were later to call him Sir Almost Right, this did not seriously affect scientific advance); Howell and Holt, who in 1917 assigned no clinical importance to heparin except as a cause of hemophilia; and Hering (1923) and Koch and Mies (1929), who thought that ineffective carotid sinus function was an important cause of hypertension in man. The other 46 tossed out good ideas later shown to be worthy of the further investigation of them by others.

If this analysis of randomly selected articles suggests that speculation has greater potential for good than for harm, why do scientific articles contain little or no speculation?

(1) First is the ancient dictum that "a scientist must never go beyond his facts."

(2) Even though speculation is put into a separate section and boldly labeled, it may still come through to some readers as "conclusions."

(3) Space in journals is expensive and when a reviewer of a manuscript says "cut it in half," the first thing to go is speculation.

(4) A serious problem, especially for young investigators, is that speculation gives away to others an author's best ideas for future research which he is entitled to follow up, at least within a reasonable period of time. Speculation by scientists working in industrial scientific laboratories of course gives competitors leads to highly profitable products.

(5) A closely related problem is that speculation can be an unethical device for an author to claim later on that an important discovery was really his work though he put in no actual experimental time or effort to establish the validity of his idea.

(6) Finally, there's the rationalization that it's not worth the effort because "you can lead a horse to water but you can't make him drink."

I believe that the time has now come when we should give speculation a fair trial and evaluate its impact on scientific advance. It could provide worthwhile research projects for those who cannot distinguish between the more and the less important or for those who lack originality but are technically superb at completing important research projects proposed by others (and I think many horses will drink water from another well when they realize theirs is dry). It might put to an experimental test some ideas that otherwise die when a brilliant scientists dies. And if we could bring together into one journal well-edited speculation from many fields of science, we might speed entry of a whole new set of ideas and concepts into biomedical research and greatly extend the scope of a scientist's reading.

Finally, if we believe in the power of private enterprise, here's a way of letting individual scientists decide for themselves which of many promising leads to explore instead of being "directed" by non-scientists who are convinced that *someone* must act.

**Julius H. Comroe, Jr.**

*All of these were "key articles" crucial to clinical advances in cardiovascular medicine or surgery (19).

## Addendum

I'd like to see speculation become a respected and valuable component of each scientific article in each journal, but it seems easier to start a new journal than to change an existing one! Just about 20 years ago a new journal, *Perspectives in Biology and Medicine*, appeared, "designed to communicate heuristic ideas," and invited readers to submit new hypotheses and concepts. Although its articles have always been interesting to read, relatively few have dealt specifically with "generalizations, working hypotheses, leisurely interpretation and speculation that the reader might carry to the laboratory and to the bedside," and I don't think it has fulfilled its promise.

Recently another journal, *Medical Hypotheses*, has appeared on the scene (20). Let David F. Horrobin, its editor, tell why he added one more to the 3,000 biomedical journals now in existence:

> The physical and chemical sciences long ago recognized that observations are not superior to hypotheses in generating scientific progress nor are hypotheses superior to observations. Both are necessary. While the ideal research worker may be one who is equally able to generate hypotheses and to test them experimentally, these sciences also recognized that such paragons are very rare indeed. Most scientists are much better at either one or the other activity. In physicochemical fields this is fully accepted and the contributions of both theoretical and experimental scientists are recognized.
>
> In contrast in the biomedical sciences there seems to me much ignorance of the way in which scientific advance actually occurs.... [Biologists] have failed to recognize adequately that observation is always more effective when disciplined and channelled by hypothesis.... Most scientists now active in the biomedical field are competent observers whose ability to generate ideas is either naturally absent or has been stultified by the prevailing philosophy. As a result they spend their time in making more and more detailed observations of the same sorts of phenomena. In contrast a few have far more ideas than they could possibly investigate but their potential contribution is largely nullified because they are allowed to publish only in those areas where they have done experimental or clinical work. If only these differences of ability and emphasis could be accepted and recognized then the people with ideas (who may often be inept experimenters) could generate a steady flow of new concepts which might rejuvenate the work of those whose primary skill is in observation.

*Medical Hypotheses* won't accomplish my goal of sprinkling reasonable, legitimate speculation in each article in each journal: it won't reach many individual subscribers ($60/6 issues) or carry many hypotheses to them (about eight articles every two months)—but it's a brave start. If it doesn't let history, philosophy, sociology, and politics of science crowd out hypotheses, journal #3,001 should be a valuable addition to the present 3,000.

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Notices of competitions, scholarships, fellowships, examination dates, new educational programs, and the like will be listed here free of charge. Items for the Notices section must reach the Journal 60 days before the desired month of publication (January 1 for the March issue, February 1 for the April issue, etc). Include all pertinent information and mail notices to RESPIRATORY CARE Notices Dept, 11030 Ables Lane, Dallas TX 75229-4593

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RESPIRATORY CARE

# Manuscript Preparation Guide

## General Information

RESPIRATORY CARE welcomes original manuscripts related to respiratory care and prepared according to these Instructions. Manuscripts are blinded and reviewed by professionals who are experts in their fields. Authors are responsible for all aspects of the manuscript and receive galleys to proofread before publication. Each accepted manuscript is copyedited so that its message is clear and it conforms to the Journal's style. Published papers are copyrighted by Daedalus Inc and may not be published elsewhere without permission.

Editorial consultation is available at any stage of planning or writing. On request, specific guidance is provided for all publication categories. These Instructions and related materials are available. Write to RESPIRATORY CARE, 11030 Ables Lane, Dallas TX 75229-4593, call (214) 243-2272, or fax (214) 484-6010.

## Publication Categories & Structure

**Research Article:** A report of an original investigation (a study). It includes a Title Page, Abstract, Introduction, Methods, Results, Discussion, Conclusions, Product Sources, Acknowledgments, References, Tables, Appendices, Figures, and Figure Captions.

**Evaluation of Device/Method/Technique:** A description and evaluation of an old or new device, method, technique, or modification. It has a Title Page, Abstract, Introduction, Description of Device/Method/Technique, Evaluation Methods, Evaluation Results, Discussion, Conclusions, Product Sources, Acknowledgments, References, Tables, Appendices, Figures, and Figure Captions.

**Case Report:** A report of a clinical case that is uncommon, or was managed in a new way, or is exceptionally instructive. All authors must be associated with the case. A case-managing physician must either be an author or furnish a letter approving the manuscript. Its components are Title Page, Abstract, Introduction, Case Summary, Discussion, References, Tables, Figures, and Figure Captions.

**Review Article:** A comprehensive, critical review of the literature and state-of-the-art summary of a pertinent topic that has been the subject of at least 40 published research articles. Title Page, Outline, Introduction, Review of the Literature, Summary, Acknowledgments, References, Tables, Appendices, and Figures and Captions may be included.

**Overview:** A critical review of a pertinent topic that has fewer than 40 published research articles.

**Update:** A report of subsequent developments in a topic that has been critically reviewed in this Journal or elsewhere.

**Point-of-View Paper:** A paper expressing personal but substantiated opinions on a pertinent topic. Title Page, Text, References, Tables, and Illustrations may be included.

**Special Article:** A pertinent paper not fitting one of the foregoing categories may be acceptable as a Special Article. Consult with the Editor before writing or submitting such a paper.

**Editorial:** A paper drawing attention to a pertinent concern; it may present an opposing opinion, clarify a position, or bring a problem into focus.

**Letter:** A signed communication about prior publications in this Journal or about other pertinent topics. Tables and illustrations may be included. Mark "For publication."

**Blood Gas Corner:** A brief, instructive case report involving blood-gas values—with Questions, Answers, and Discussion.

**Drug Capsule:** A mini-review paper about a drug or class of drugs that includes discussions of pharmacology, pharmacokinetics, and pharmacotherapy.

**Kittredge's Corner:** A brief description of the operation of respiratory care equipment—with information from manufacturers and editorial comments and suggestions.

**PFT Corner:** Like Blood Gas Corner, but involving pulmonary function tests.

**Cardiorespiratory Interactions.** A case report demonstrating the interaction between the cardiovascular and respiratory systems. It should be a patient-care scenario; however, the case—the central theme—is the systems interaction. CRI is characterized by figures, equations, and a glossary. See the March 1996 issue of RESPIRATORY CARE for more detail.

**Test Your Radiologic Skill:** Like Blood Gas Corner, but involving pulmonary medicine radiography and including one or more radiographs, may involve imaging techniques other than conventional chest radiography.

**Review of Book, Film, Tape, or Software:** A balanced, critical review of a recent release.

### Preparing the Manuscript

Print on one side of white bond paper, 8.5 in. x 11 in. (216 x 279 mm) with margins of at least 1 in. (25 mm) on all sides of the page. Use ***double-spacing*** throughout the ***entire*** manuscript. Use a standard font (eg, Times, Helvetica, or Courier) at least 10 points in size, and do not use italics except for special emphasis. Number all pages in upper-right corners. Indent paragraphs 5 spaces. Do ***not justify***. Do ***not*** put authors' names or other identification anywhere except on the title page. Repeat title only (no authors) on the abstract page. Begin each of the following on a new page: Title Page, Abstract, Text, Product-Sources List, Acknowledgments, References, each Table, and each Appendix. Use standard English in the first person and active voice.

Center main section headings on the page and type them in capital and small letters (eg, Introduction, Methods, Results, Discussion). Begin subheadings at the left margin and type them in capital and small letters (eg, Patients, Equipment, Statistical Analysis).

**References.** Cite only published works as references. Manuscripts accepted but not yet published may be cited as references: designate the accepting journal, followed by (in press). Please provide 3 copies of the in-press article for reviewer inspection. Cite references in the text with superscript numerals. Assign numbers in the order that references are first cited. On the reference page, list the cited works in numerical order. Follow the Journal's style for references. Abbreviate journal names as in *Index Medicus*. List all authors.

Article in a journal carrying pagination throughout volume:

1. Rau JL, Harwood RJ. Comparison of nebulizer delivery methods through a neonatal endotracheal tube: a bench study. Respir Care 1992;37(11):1233-1240.

Article in a publication that numbers each issue beginning with Page 1:

2. Bunch D. Establishing a national database for home care. AARC Times 1991;15(Mar):61,62,64

Corporate author journal article:

3. American Association for Respiratory Care. Criteria for establishing units for chronic ventilator-dependent patients in hospitals. Respir Care 1988;33(11):1044-1046.

Article in journal supplement: (Journals differ in their methods of numbering and identifying supplements. Supply sufficient information to promote retrieval.)

4. Reynolds HY. Idiopathic interstitial pulmonary fibrosis. Chest 1986;89(3, Suppl):139S-143S.

Abstract in journal: (Abstracts citations are to be avoided. Those more than 3 years old should not be cited.)

5. Stevens DP. Scavenging ribavirin from an oxygen hood to reduce environmental exposure (abstract). Respir Care 1990;35(11): 1087-1088.

Editorial in journal:

6. Enright P. Can we relax during spirometry? (editorial). Am Rev Respir Dis 1993;148(2):274

Editorial with no author given:

7. Negative-pressure ventilation for chronic obstructive pulmonary disease (editorial). Lancet 1992;340(8833):1440-1441.

Letter in journal:

8. Aelony Y. Ethnic norms for pulmonary function tests (letter). Chest 1991;99(4):1051.

Paper accepted but not yet published:

9. Hess D. New therapies for asthma. Respir Care (year, in press).

Personal author book: (For any book, specific pages should be cited whenever possible.)

10. DeRemee RA. Clinical profiles of diffuse interstitial pulmonary disease. New York: Futura, 1990:76-85.

Corporate author book:

11. American Medical Association Department of Drugs. AMA drug evaluations, 3rd ed. Littleton CO: Publishing Sciences Group, 1977.

Chapter in book with editor(s):

12. Pierce AK. Acute respiratory failure. In: Guenter CA, Welch MH, editors. Pulmonary medicine. Philadelphia: JB Lippincott, 1977.

**Tables.** Use consecutively numbered tables to display information. Start each table on a separate page. Number and title the table and give each column a brief heading. Place explanations in footnotes, including all nonstandard abbreviations and symbols. Key the footnotes with conventional designations (asterisk, dagger, double dagger, etc) in consistent order, placing them superscript in the table body. Do not use horizontal or vertical rules or borders. Do not submit tables as photographs, reduced in size, or on oversize paper. Use the same typeface as in the text.

**Illustrations.** Graphs, line drawings, photographs, and radiographs are figures. Use only illustrations that clarify and augment the text. Number them consecutively as Fig. 1, Fig. 2, and so forth according to the order by which they are mentioned in the text. Be sure all figures are cited. If any figure was previously published, include copyright holder's written permission to reproduce. Figures for publication must be of professional quality. Data for the original graphs should be available to the Editor upon request. If color is essential, consult the Editor for more information. In reports of animal experiments, use schematic drawings, not photographs. A letter of consent must accompany any photograph of a person. Do not place titles and detailed explanations on figures; put this information in figure captions. If possible, submit radiographs as prints and full-size copies of film.

**Drugs.** Identify precisely all drugs and chemicals used, giving generic names, doses, and routes of administration. If desired, brand names may be given in parentheses after generic names. Drugs should be listed on the product-sources page.

**Commercial Products.** In parentheses in the text, identify any commercial product (including model number if applicable) the first time it is mentioned, giving the manufacturer's name, city, and state or country. If four or more products are mentioned, do not list any manufacturers in the text; instead, list them on a Product Sources page at the end of the text, before the References. Provide model numbers when available and manufacturer's suggested price, if the study has cost implications.

**Ethics.** When reporting experiments on human subjects, indicate that procedures were conducted in accordance with the ethical standards of the institution's committee on human experimentation. State that informed consent was obtained. Do not use patient's names, initials, or hospital numbers in text or illustrations. When reporting experiments on animals, indicate that the institution's policy, a national guideline, or a law on the care and use of laboratory animals was followed.

**Statistics.** Identify the statistical tests used in analyzing the data, and give the prospectively determined level of significance in the Methods section. Report actual p-values in Results. Cite only textbook and published article references to support choices of tests. Identify any general-use or commercial computer programs used, naming manufacturers and their locations. These should be listed on the product-sources page.

**Units of Measurement.** Express measurements of length, height, weight, and volume in metric units appropriately abbreviated; temperatures in degrees Celsius; and blood pressures in millimeters of mercury (mm Hg). Report hematologic and clinical-chemistry measurements in conventional metric and in SI (Systémé Internationale) units. Show gas pressures (including blood gas tensions) in torr. List SI equivalent values, when possible, in brackets following non-SI values—for example, "PEEP, 10 cm $H_2O$ [0.981 kPa]." For conversion to SI, see RESPIRATORY CARE 1988;33(10):861-873 (Oct 1988) and 1989;34(2):145 (Feb 1989).

**Conflict of Interest.** Authors are asked to disclose any liaison or financial arrangement they have with a manufacturer or distributor whose product is part of the submitted manuscript or with the manufacturer or distributor of a competing product. (Such arrangements do not disqualify a paper from consideration and are not disclosed to reviewers.) A statement to this effect is included on the cover-letter page.

**Abbreviations and Symbols.** Use standard abbreviations and symbols. Avoid creating new abbreviations. Avoid all abbreviations in the title and unusual abbreviations in the abstract. Use an abbreviation only if the term occurs several times in the paper. Write out the full term the first time it appears, followed by the abbreviation in parentheses. Thereafter, employ the abbreviation alone. Never use an abbreviation without defining it. Standard units of measurement can be abbreviated without explanation (eg, 10 L/min, 15 torr, 2.3 kPa).

Please use the following forms: cm $H_2O$ (not cmH2O), f (not bpm), f (not f), L/min (not LPM, l/min, or lpm), mL (not ml), mm Hg (not mmHg), pH (not Ph or PH), $p > 0.001$ (not p>0.001), s (not sec), $S_{pO_2}$ (pulse-oximetry saturation)

**Submitting the Manuscript**

Mail three copies of the manuscript, figures, diskette, and the Cover Letter & Checklist to RESPIRATORY CARE, 11030 Ables Lane, Dallas TX 75229-4593. Do not fax manuscripts. Protect figures with cardboard. Keep a copy of the manuscript and figures. Receipt of your manuscript will be acknowledged.

**Computer Diskettes.** A manuscript may be submitted on a Macintosh or IBM-DOS diskette. Macintosh documents on 3.5 in. diskettes written in Microsoft Word versions 4.0 and 5.0 are preferred. However, we can convert most documents (including PC-DOS format) to our format. Label each diskette with date; author's name; name of word-processing program and version used to prepare documents; and filename(s). Do not write on a diskette except with a felt-tipped pen. Tables and figures must be in their own separate files, with software identified. Supply 3 hard copies of the manuscript with the diskette.

**Prior and Duplicate Publication.** Work that has been published or accepted elsewhere should not be submitted. In special instances, the Editor may consider such material, provided that permission to publish is given by the author and original publisher. Please consult the Editor before submitting such work.

**Authorship.** All persons listed as authors should have participated in the reported work and in the shaping of the manuscript; all must have proofread the submitted manuscript; and all should be able to publicly discuss and defend the paper's content. A paper with corporate authorship must specify the key persons responsible for the article. Authorship is not justified solely on the basis of solicitation of funding, collection or analysis of data, provision of advice, or similar services. Persons who provide such ancillary services exclusively may be recognized in an Acknowledgments section.

**Permissions.** The manuscript must be accompanied by copies of permissions to reproduce previously published material (figures or tables); to use illustrations of, or report sensitive personal information about, identifiable persons; and to name persons in the Acknowledgments section.

**Reviewers.** Please supply the names, credentials, affiliations, addresses, and phone/fax numbers of three professionals whom you consider expert on the topic of your paper. Your manuscript may be sent to one or more of them for blind peer review.

**Editorial Office:**

RESPIRATORY CARE
11030 Ables Lane
Dallas TX 75229-4593
(214) 243-2272 (telephone)
(214) 484-6010 (fax)

## Cover Letter & Checklist

A copy of this completed form must accompany all manuscripts submitted for publication.

Title of Paper: _____

Publication Category: _____

Authors: _____

Author to be Contacted: _____ Phone: _____ FAX: _____

Mailing Address of Contact Author: _____

Reprints: Yes No

"We, the undersigned, have all participated in the work reported, proofread the accompanying manuscript, and approve its submission for publication." Please print and include credentials, title, institution, academic appointments, city and state. If more than 4 authors, please use another copy of this form.*

*Author Data: _____

Author Signature/Date _____

*Author Data: _____

Author Signature/Date _____

*Author Data: _____

Author Signature/Date _____

*Author Data: _____

Author Signature/Date _____

Has this research been presented in a public forum? Yes No

If yes, where, when and by whom? _____

Has this research received awards? Yes No

If yes, please describe. _____

Do any of the authors have a financial interest in the products mentioned in this paper or competing products?

Yes No If yes, please disclose: _____

**Checklist:**

- Is double-spacing used throughout entire manuscript?
- Are all pages numbered in upper-right corners?
- Are all references, figures, and tables cited in the text?
- Has the accuracy of the references been checked, and are they correctly formatted?
- Have SI values been provided?
- Has all arithmetic been checked?
- Have generic names of drugs been provided?
- Have necessary written permissions been provided?
- Have authors' names been omitted from text and figure labels?
- Have copies of 'in press' references been provided?
- Has the manuscript been proofread by all the authors?

# New Products & Services

News releases about new products and services will be considered for publication in this section. There is no charge for these listings. Send descriptive release and glossy black and white photographs to RESPIRATORY CARE Journal, New Products and Services Dept, 11030 Ables Lane, Dallas TX 75229-4593

**$O_2$ CONCENTRATOR.** DeVilbiss introduces the SolAiris Series of $O_2$ concentrators. According to DeVilbiss, the SolAiris III is a compact 3-L unit, and the SolAiris V is a flexible, 5-L concentrator— both are designed to provide patient-friendly operation and portability. The SolAiris III weighs 37 pounds and has handles, grips, and 4 casters, 2 of which are front-locking. In addition, it features a dual-head compressor, single-solenoid valve, low wattage, and 93 ± 3% concentration at every liter flow. The SolAiris V is equipped with the Dura-Aire compressor with a 5-year life and warranty. Both offer an interrupt alarm without a battery, a pressure sensing system that adjusts to pressure changes at varying altitudes, a self-diagnostic system with LED sequence, audible diagnostics, and a memory button for viewing the light sequence after the unit is turned off. Circle reader service card number 90 for more details.

**INTERACTIVE SOFTWARE.** Innovative Solutions for Health Care introduces the interactive computer program QuizMaster RRT, created for student practitioners. The program, according to the company, features randomly generated questions for self-study, prepares the student for national board examinations, and points out the student's strengths while emphasizing areas that require more study. The program may also be challenging to experienced therapists. Quiz Master RRT requires an IBM-compatible personal computer with Windows 3.1 ™ or Windows 95 ™. For details, circle reader service card number 91, or contact Innovative Solutions via the Internet at http://www.portal.ca/~innov/innov.html.

**HIGH PRESSURE DOMES.** Spectra Medical Devices Inc offers high pressure domes that work with reusable transducers. The company says that the domes are constructed of a sturdy polycarbonate body with a clear silicone or polycarbonate membrane, UPS class six materials. All fluid pathways are certified to be medical grade and are 510K approved. For more information, circle reader service card number 92.

**PATIENT EDUCATION BOOKLET.** The American Academy of Allergy Asthma & Immunology and Glaxo Wellcome Inc offer a patient education booklet designed to help patients manage asthma. According to the designers, *Making the Most of Your Next Doctor Visit: A Personal Asthma Management Monitor* encourages asthma sufferers to pay attention to how asthma affects their health and lives. Patients are also given an easy-to-use chart that helps them record their symptoms and communicate with their doctor so that a treatment plan can be tailored to their specific needs. For a booklet, circle reader service card number 93.

**CLEANING SYSTEM.** Geddis Incorporated releases the SurgiSonic™ Cleaning System. Geddis claims that the SurgiSonic is designed specifically to clean the tight-fitting interiors of both laparoscopic and endoscopic forceps. The system uses a combination of ultrasound, channeled suction, and filtration to loosen, remove, and trap debris from the instrument's interior. Three instruments may be cleaned at one time. A 30-minute cleaning cycle pulls water through a 220-cm endoscopic forceps 5 times. For details about the SurgiSonic's 2-week trial period, circle reader service card number 94.

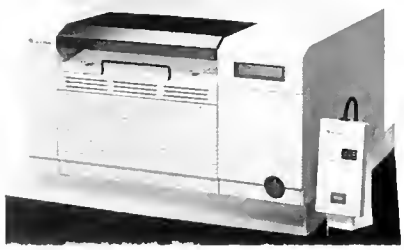
**QUALITY ASSURANCE PROGRAM.** Nova Biomedical recently created a peer group comparison program for Nova electrolyte analyzers. The free Quality Assurance Program provides

statistical peer group analysis, simplifies record keeping, and satisfies regulatory and maintenance requirements, the company claims. Unassayed control material is sequestered for specific laboratory needs and sent to participating laboratories. Results may be logged in on control report forms or tabulated on a computer and returned to Nova. Nova reviews the monthly results and provides a peer group comparison of the analyzer. Circle reader service card number 95 for more information about the free program.

**SPIROMETRY SYSTEM.** Burdick Inc introduces the Presto Stand-Alone Spirometry System. The system features a compact, user-friendly design with an easy-to-read display; and, with the use of a standard 3-L syringe, the Presto can be calibrated to American Thoracic Society recommendations, Burdick claims. The Presto offers user-selected predicted normal values, maneuver acceptability-reproducibility checks, calculation and comparison of both pre- and post-BD test results, and interpretations. Other features include full reports in less than 30 seconds, COPD risk assessment, and lung-age calculations. The flow-sensor insert can be removed for autoclave, gas, or cold-disinfectant cleaning. For more details, circle reader service card number 96.

**VENTILATOR SYSTEM.** Bird Products Corporation announces the TBird Ventilator Systems. According to Bird, TBird is a self-contained system that uses turbine technology with an internal or optional external battery for uninterrupted mechanical ventilation of critically ill patients. The system has safety features such as apnea back-up ventilation, a locking mechanism to prevent accidental changes in control settings, color-coded controls that are easy to read and set, and a central knob for 1-button operation. For more information about the TBird system, circle reader service card number 97.

**OZONE DETECTOR.** CEA Instruments Inc lists the TG-800KA portable ozone ($O_3$) gas monitor as a newly available product. The monitor, according to the manufacturer, can detect $O_3$ at 0.01 ppm. The patented gas membrane galvanic cell sensor never needs to be replaced, and the internal battery is rechargeable to 30 hours. The lightweight monitor is portable and contains a battery charger, AC power supply, and recorder output. For information about the detector, circle reader service card number 98.



**VIDEO IMAGER.** Fuji Medical Systems U.S.A. Inc releases the Fuji FTI-1000 Thermal Imaging System that prints up to 6 images on a single sheet of transparent or reflective polyester, FDA-approved film. According to Fuji, the film can be archived for more than 10 years without image degradations. The system accepts images from most medical imaging modalities that use a variable line rate video signal, including those from the cardiac catheterization laboratory, ultrasound, nuclear medicine, computed tomography scans, and magnetic resonance imaging. The imager can provide a print in about 60 seconds; each roll of film can produce 100 prints or more. Options are available, circle reader service card number 99.

**INFANT NEBULIZER.** PARI Respiratory Equipment Inc introduces the PARI Baby™ medication delivery system. Designed for the treatment of asthma in babies and infants, the system is a reusable nebulizer with a soft, silicone face mask. For newborns to 3 year olds, the mask is available in 3 sizes. According to the company, the elbow attachment can be rotated to allow medication delivery while the baby is sleeping, sitting in a parent's lap or stroller, or while the child is standing. PARI Baby is designed for in-home use and can be cleaned in the dishwasher or boiled. Circle reader service card number 100 for a free information packet.

# Don't Miss the Research Symposium at the 42nd International Convention & Exhibition in San Diego

Presented by the Editorial Board of
RESPIRATORY CARE
Wednesday, November 6
9:00-10:55 am • Rooms 1A-B

9:00-9:15 am
**Program Overview**
Joseph L Rau Jr PhD RRT
Georgia State University, Atlanta GA /*Chairing*
Introduces and reviews the 1993-1995 symposium topics and the key topics of knowledge in a research project.

9:20-10:05 am
**Ethics of Human Research and Institutional Review Boards**
Dean R Hess PhD RRT
Massachusetts General Hospital, Boston MA
Defines "ethics." Explains the rationale for board regulations, using examples. Outlines regulations: exempt, expedited, full review studies. Details the key elements in an Informed Consent Form.

10:10-10:55 am
**Population and Samples: Concepts and Examples**
Joseph L Rau Jr PhD RRT
Describes two examples of sample results. Defines terms: target population, accessible population, sample. Explains analysis of examples using these distinctions. Details example of population criteria used to select a nonrandom sample.

# Respiratory Care and Medical Direction in a Changing World

## Saturday, November 2

During the 42nd International Convention & Exhibition, the AARC and Vanderbilt University will present this one-day post-graduate course for physicians only.

The program is approved for 7 hours in Category I of the Physician's Recognition Award of the American Medical Association. Topics include the future of respiratory care, a primer on concepts and terms in health care today, the role of the medical director in today's hospital, medical direction beyond the acute care hospital, an update on ARDS, patient protocols and clinical pathways in respiratory care, clinical practice guidelines, departmental restructuring, and how to select ventilators.

Encourage your medical director to attend this informative program. The $225 tuition entitles physicians to complimentary registration to the AARC International Convention & Exhibition.

**Contact** Robert Czachowski, PhD, Director of Education, AARC, today at 214-243-2272 (Fax 214-484-2720) and request that a complete description of the course and registration form be sent to your medical director or other interested physician.

# American Association for Respiratory Care Membership Application

Please read the eligibility requirements for each of the classifications in the right-hand column, then complete the applicable section. All information requested below must be provided, except where indicated as optional. See other side for more information and fee schedule. Please sign and date application on reverse side and type or print clearly. Processing of application takes approximately 15 days.

- ☐ Active
- Associate
  - ☐ Foreign
  - ☐ Physician
  - ☐ Industrial
- ☐ Special
- ☐ Student

Last Name _____

First Name _____ Middle _____

Social Security No. _____

Home Address _____

City _____

State _____ Zip __ __ __ __ __ - __ __ __ __

Phone No. (_____) _____

**Primary Job Responsibility (check one only)**

- ☐ Technical Director
- ☐ Assistant Technical Director
- ☐ Pulmonary Function Specialist
- ☐ Instructor/Educator
- ☐ Supervisor
- ☐ Staff Therapist
- ☐ Staff Technician
- ☐ Rehabilitation/Home Care
- ☐ Medical Director
- ☐ Sales
- ☐ Student
- ☐ Other, specify _____

**Type of Business**

- ☐ Hospital
- ☐ Skilled Nursing Facility
- ☐ DME/HME
- ☐ Home Health Agency
- ☐ Educational Institution
- ☐ Manufacturer or supplier
- ☐ Other, specify _____

Date of Birth (optional) _____ Sex (optional) _____

U.S. Citizen? ___ Yes ___ No

Have you ever been a member of the AARC? _____

If so, when? From _____ to _____

Preferred mailing address: ☐ Home ☐ Business

## *FOR ACTIVE MEMBER*

An individual is eligible if he/she lives in the U.S. or its territories or was an Active Member prior to moving outside its borders or territories, and meets ONE of the following criteria: (1) is legally credentialed as a respiratory care professional if employed in a state that mandates such, OR (2) is a graduate of an accredited educational program in respiratory care, OR (3) holds a credential issued by the NBRC. An individual who is an AARC Active Member in good standing on December 8, 1994 will continue as such provided his/her membership remains in good standing.

Place of Employment _____

_____

Address _____

City _____

State _____ Zip __ __ __ __ __ - __ __ __ __

Phone No. (_____) _____

Medical Director/Medical Sponsor _____

## *FOR ASSOCIATE OR SPECIAL MEMBER*

Individuals who hold a position related to respiratory care but do not meet the requirements of Active Member shall be Associate Members. They have all of the rights and benefits of the Association except to hold office, vote, or serve as chair of a standing committee. The following subclasses of Associate Membership are available: Foreign, Physician, and Industrial (individuals whose primary occupation is directly or indirectly devoted to the manufacture, sale, or distribution of respiratory care equipment or supplies). Special Members are those not working in a respiratory care-related field.

PLEASE USE THE ADDRESS OF THE LOCATION WHERE YOU PERFORM YOUR JOB, NOT THE CORPORATE HEADQUARTERS IF IT IS LOCATED ELSEWHERE.

Place of Employment _____

_____

Address _____

City _____

State _____ Zip __ __ __ __ __ - __ __ __ __

Phone No. (_____) _____

## *FOR STUDENT MEMBER*

Individuals will be classified as Student Members if they meet all the requirements for Associate Membership and are enrolled in an educational program in respiratory care accredited by, or in the process of seeking accreditation from, an AARC-recognized agency.

SPECIAL NOTICE — Student Members do not receive Continuing Respiratory Care Education (CRCE) transcripts. Upon completion of your respiratory care education, continuing education credits may be pursued upon your reclassification to Active or Associate Member.

School/RC Program _____

_____

Address _____

City _____

State _____ Zip __ __ __ __ __ - __ __ __ __

Phone No. (_____) _____

**Length of Program**

- 1 year
- 2 years
- ☐ 4 years
- ☐ Other, specify _____

**Expected Date of Graduation (REQUIRED INFORMATION)**

Month_____ Year_____

**American Association for Respiratory Care • 11030 Ables Lane • Dallas, TX 75229-4593 • (214) 243-2272 • FAX (214) 484-2720**

# American Association for Respiratory Care Membership Application

## Demographic Questions

We request that you answer these questions in order to help us design services and programs to meet your needs.

**Check the Highest Degree Earned**

- ☐ High School
- ☐ RC Graduate Technician
- ☐ Associate Degree
- ☐ Bachelor's Degree
- ☐ Master's Degree
- ☐ Doctorate Degree

**Number of Years in Respiratory Care**

- ☐ 0-2 years
- ☐ 3-5 years
- ☐ 6-10 years
- ☐ 11-15 years
- ☐ 16 years or more

**Job Status**

- ☐ Full Time
- ☐ Part Time

**Credentials**

- ☐ RRT
- ☐ CRTT
- ☐ Physician
- ☐ CRNA
- ☐ RN
- ☐ LVN/LPN
- ☐ CPFT
- ☐ RPFT
- ☐ Perinatal/Pediatric

**Salary**

- ☐ Less than $10,000
- ☐ $10,001-$20,000
- ☐ $20,001-$30,000
- ☐ $30,001-$40,000
- ☐ $40,001 or more

**PLEASE SIGN**

I hereby apply for membership in the American Association for Respiratory Care and have enclosed my dues. If approved for membership in the AARC, I will abide by its bylaws and professional code of ethics. I authorize investigation of all statements contained herein and understand that misrepresentations or omissions of facts called for is cause for rejection or expulsion.

A yearly subscription to **Respiratory Care** journal and **AARC Times** magazine includes an allocation of $6.50 from my dues for each of these publications.

*NOTE: Contributions or gifts to the AARC are not tax deductible as charitable contributions for income tax purposes. However, they may be tax deductible as ordinary and necessary business expenses subject to restrictions imposed as a result of association lobbying activities. The AARC estimates that the nondeductible portion of your dues - the portion which is allocable to lobbying - is 26%.*

**Signature** _____

**Date** _____

## Membership Fees

Payment must accompany your application to the AARC. Fees are for 12 months. (NOTE: Renewal fees are $65.00 Active, Associate-Industrial or Associate-Physician, or Special status; $80.00 for Associate-Foreign status; and $35.00 for Student status.)

| | |
|---|---|
| ☐ Active | $77.50 |
| ☐ Associate (Industrial or Physician) | $77.50 |
| ☐ Associate (Foreign) | $92.50 |
| ☐ Special | $77.50 |
| ☐ Student | $35.00 |
| TOTAL | $_____ |

***Specialty Sections***

Established to recognize the specialty areas of respiratory care. The sections publish a newsletter four times a year that focuses on issues of specific concern to that specialty. The sections also design the specialty programming at the national AARC meetings.

| | |
|---|---|
| ☐ Adult Acute Care Section | $ 5.00 |
| ☐ Education Section | $10.00 |
| ☐ Perinatal-Pediatric Section | $ 5.00 |
| ☐ Diagnostics Section | $ 5.00 |
| ☐ Continuing Care-Rehabilitation Section | $ 5.00 |
| ☐ Management Section | $10.00 |
| ☐ Transport Section | $ 5.00 |
| ☐ Home Care | $ 5.00 |
| ☐ Subacute Care | $ 5.00 |
| TOTAL | $_____ |

**GRAND TOTAL = Membership Fee plus optional sections $_____**

---

☐ Total Amount Enclosed $_____

☐ Please charge my dues (see below)

To charge your dues, complete the following:

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**Mail Application and Appropriate Fees To:**

**American Association for Respiratory Care • 11030 Ables Lane • Dallas • TX 75229-4593 • (214) 243-2272 • FAX (214) 484-2720**

# MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY reporting by health professionals of adverse events and product problems

Page of

Form Approved OMB No 0910-0291 Expires 4/30/96
See OMB statement on reverse

FDA Use Only (Resp Care)

Triage unit sequence #

## A. Patient information

1 Patient identifier
In confidence

2. Age at time of event:
or
Date of birth:

3. Sex
☐ female
☐ male

4 Weight
_____ lbs
or
_____ kgs

## B. Adverse event or product problem

1 ☐ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
☐ death _____ (mo/day/yr)
☐ life-threatening
☐ hospitalization – initial or prolonged
☐ disability
☐ congenital anomaly
☐ required intervention to prevent permanent impairment/damage
☐ other

3 Date of event (mo/day/yr)

4 Date of this report (mo/day/yr)

5 Describe event or problem

6 Relevant tests/laboratory data, including dates

7 Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

## C. Suspect medication(s)

1 Name (give labeled strength & mfr/labeler, if known)
#1
#2

2 Dose, frequency & route used
#1
#2

3 Therapy dates (if unknown, give duration) (from/to or best estimate)
#1
#2

4 Diagnosis for use (indication)
#1
#2

5 Event abated after use stopped or dose reduced
#1 ☐ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

6 Lot # (if known)
#1
#2

7 Exp. date (if known)
#1
#2

8 Event reappeared after reintroduction
#1 ☐ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

9 NDC # (for product problems only)
– –

10 Concomitant medical products and therapy dates (exclude treatment of event)

## D. Suspect medical device

1 Brand name

2 Type of device

3 Manufacturer name & address

4 Operator of device
☐ health professional
☐ lay user/patient
☐ other

5. Expiration date (mo/day/yr)

6
model #
catalog #
serial #
lot #
other #

7 If implanted, give date (mo/day/yr)

8 If explanted, give date (mo/day/yr)

9 Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on _____ (mo/day/yr)

10 Concomitant medical products and therapy dates (exclude treatment of event)

## E. Reporter (see confidentiality section on back)

1 Name & address

phone #

2 Health professional?
☐ yes ☐ no

3 Occupation

4 Also reported to
☐ manufacturer
☐ user facility
☐ distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. ☐

FDA

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

FDA Form 3500 1/96)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

# ADVICE ABOUT VOLUNTARY REPORTING

**Report experiences with:**

- medications (drugs or biologics)
- medical devices (including in-vitro diagnostics)
- special nutritional products (dietary supplements, medical foods, infant formulas)
- other products regulated by FDA

**Report SERIOUS adverse events. An event is serious when the patient outcome is:**

- death
- life-threatening (real risk of dying)
- hospitalization (initial or prolonged)
- disability (significant, persistent or permanent)
- congenital anomaly
- required intervention to prevent permanent impairment or damage

**Report even if:**

- you're not certain the product caused the event
- you don't have all the details

**Report product problems** – quality, performance or safety concerns such as:

- suspected contamination
- questionable stability
- defective components
- poor packaging or labeling
- therapeutic failures

**How to report:**

- just fill in the sections that apply to your report
- use section C for all products except medical devices
- attach additional blank pages if needed
- use a separate form for each patient
- report either to FDA or the manufacturer (or both)

**Important numbers:**

- 1-800-FDA-0178 to FAX report
- 1-800-FDA-7737 to report by modem
- 1-800-FDA-1088 to report by phone or for more information
- 1-800-822-7967 for a VAERS form for vaccines

**If your report involves a serious adverse event with a device** and it occurred in a facility outside a doctor's office, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.

**Confidentiality:** The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. The reporter's identity, including the identity of a self-reporter, may be shared with the manufacturer unless requested otherwise. However, FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act.

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DHHS Reports Clearance Office
Paperwork Reduction Project (0910-0291)
Hubert H. Humphrey Building, Room 531-H
200 Independence Avenue, S.W.
Washington, DC 20201

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**Please do NOT return this form to either of these addresses.**

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Public Health Service • Food and Drug Administration

FDA Form 3500-back

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Rockville, MD 20857

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**Food and Drug Administration**
**5600 Fishers Lane**
**Rockville, MD 20852-9787**

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# Calendar of Events

## AARC & AFFILIATES

**September 19-20—Indiana Society**
The annual state meeting, "IRSC Today," at the Indianapolis Marriott, Indianapolis, Indiana. Contact: Cheri Bate at (317) 929-8681.

**September 19-20—Pennsylvania Society**
23rd Annual Seminar in Pulmonary Physiology and Medicine at the Sheraton Station Square, Pittsburgh, Pennsylvania. Contact: Lynda Bryner at (412) 367-5428.

**September 23—South Carolina Society**
Preconvention seminar, "Successful Strategies for Tomorrow's Respiratory Care Services," at the Hilton Hotel, Charleston, South Carolina. CRCE: 6 hours. Contact: Trish Blakely at (803) 771-5405 or Laura Lucas at (803) 771-5535.

**September 30—West Virginia Society**
Preconvention seminar, "Successful Strategies for Tomorrow's Respiratory Care Services," at the Radisson Hotel, Huntington, West Virginia. CRCE: 6 hours. Contact: Jay Wildt at (304) 442-7474 or Jean Fisher at (304) 357-4851.

**October 2-4—Kentucky Society**
Annual state meeting, "Strive for Excellence," at the Hurstborne Conference Center, Louisville, Kentucky. Contact: Janet Vogt at (502) 562-3002.

**October 11—The Southern Chapter of the Colorado Society**
3rd Annual Southern Colorado Pulmonary Medicine Symposium at the Holiday Inn Garden of the Gods, Colorado Springs, Colorado. Lunch is included in the $15 fee.
Contact: Barry Beard at (719) 776-5211, fax (719) 776-2535.

**October 15—AARC Video Conference**
"Capturing Respiratory Services Outside the Hospital—Part II: Subacute Care," Part 6 of the 1996 7-part video conference "Professor's Rounds in Respiratory Care," from 12:30 to 2 p.m. Eastern Time.
Live telephone question-and-answer session airs Nov. 18.
CRCE: 1 credit hour. Contact: AARC at (214) 243-2272.

**November 2—AARC Preconvention Postgraduate Course**
4th Annual Postgraduate Course for Physicians Only, in San Diego, California.
The 1-day program is approved for 6 hours in Category 1 of the Physician's Recognition Award of the American Medical Association.
Contact: AARC at (214) 243-2272 or fax (214) 484-2720.

**March 5-7, 1997—Journées Internationales de Ventilation à Domicile (JIVD)**
6th International Conference on Home Mechanical Ventilation, sponsored by the AARC and JIVD, in Lyon, France. The official languages of the conference are English and French; simultaneous translation will be provided. Abstracts are due by Dec. 15. For guidelines on abstract submissions and for information about the conference, contact the Congress Secretariat at JIVD, Hôpital de la Croix Rousse, Service de Réanimation Médicale et Assistance Respiratoire, 93 Grande Rue de la Croix Rousse, 69317 Lyon Cedex 04, France, or call (33) 78 39 08 43, fax (33) 78 39 58 63, or send E-mail to 100732.3540@compuserve.com.

## OTHER MEETINGS

**September 26-27—INFOCARE**
First Annual Neonatal/Pediatric Respiratory/Critical Care Symposium at the Sheraton Beach Resort in South Padre Island, Texas. Contact: INFOCARE, 350 San Roman Rd, Los Fresnos TX 78566, (210) 233-5645.

**October 4—Saint Joseph's Hospital of Atlanta**
13th Annual Respiratory Care Seminar at the hospital's auditorium in Atlanta, Georgia. Contact: Sandra Mann (404) 851-7185.

## Mark Your Calendars!

### Future AARC Conventions

**December 6-9, 1997**
**New Orleans, Louisiana**

**November 7-10, 1998**
**Atlanta, Georgia**

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5. ❑ Hosp 100 or less beds
6. ❑ Skilled Nursing Facility
7. ❑ Home Care Practice
8. ❑ School

**II. Department**
A. ❑ Respiratory Therapy
B. ❑ Cardiopulmonary
C. ❑ Anesthesia Service
D. ❑ Emergency Dept

**III. Specialty**
1. ❑ Clinical Practice
2. ❑ Perinatal Pediatrics
3. ❑ Critical Care
4. ❑ Clinical Research
5. ❑ Pulmonary Function Lab
6. ❑ Home Care/Rehab
7. ❑ Education
8. ❑ Management

**IV.Position**
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B. ❑ Chief Therapist
C. ❑ Supervisor
D. ❑ Staff Technician
E. ❑ Staff Therapist
F. ❑ Educator
G. ❑ Medical Director
H. ❑ Anesthesiologist
I. ❑ Pulmonologist
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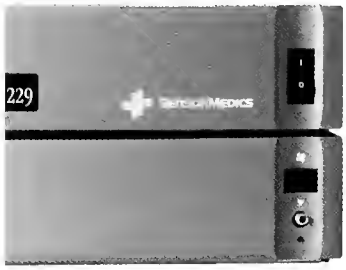


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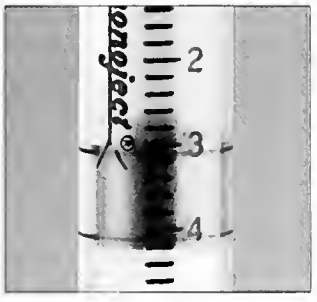


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